HEARING CONDUCTED BY THE
TEXAS STATE OFFICE OF ADMINISTRATIVE HEARINGS
SOAH DOCKET NO. 503-12-1342
LICENSE NO. D-9377

IN THE MATTER OF THE	BEFORE THE
COMPLAINT AGAINST:	
STANISLAW R. BURZYNSKI, M.D.	TEXAS MEDICAL BOARD

FIRST AMENDED COMPLAINT

TO THE HONORABLE TEXAS STATE MEDICAL BOARD AND THE HONORABLE ADMINISTRATIVE LAW JUDGE TO BE ASSIGNED:

COMES NOW, the Staff of the Texas Medical Board (Board staff), and files this Complaint against Stanislaw R. Burzynski, M.D., (Respondent), based on Respondent's alleged violations of the Medical Practice Act (Act), Title 3, Subtitle B, Texas Occupations Code, and would show the following:

I. INTRODUCTION

The filing of this Complaint and the relief requested are necessary to protect the health and public interest of the citizens of the State of Texas, as provided in Section 151.003 of the Act.

II. LEGAL AUTHORITY AND JURISDICTION

1. Respondent is a Texas Physician and holds Texas Medical License No. D-9377, issued by the Board on January 13, 1973.

2. Respondent's license was in full force and effect at all times material and relevant to this Complaint.

3. Respondent received notice of an Informal Settlement Conference (ISC). The Board complied with all procedural rules, including but not limited to, Board Rules 182 and 187, as applicable.

4. No agreement to settle this matter has been reached by the parties.

5. All jurisdictional requirements have been satisfied.

III. FACTUAL ALLEGATIONS

Board Staff has received information and relying on that information believes that Respondent has violated the Act. Based on such information and belief, Board Staff alleges:

Board Staff alleges that Respondent created a medical practice model based on marketing his proprietary anti-cancer drugs to patients without adequate measures for patient safety and therapeutic value. Respondent misled patients knowingly by promoting these drugs as an attraction to bring patients to his medical practice when Respondent was aware that he could not legally include most of those patients in FDA-approved Phase 2[1] clinical trials of his proprietary anti-cancer drugs. Respondent further misled patients into paying funds as a retainer prior to receiving any evaluation, diagnosis or treatment. Respondent further misled patients into: (1) paying exorbitant charges for drugs and medical services; (2) accepting care from unlicensed persons while Respondent and Respondent's employees misrepresented those unlicensed persons to be licensed medical doctors in Texas and the United States of America; and (3) accepting care from health care providers who had little advanced education or training related to cancer treatment while Respondent and Respondent's employees misrepresented those health care providers to be doctors with significant advanced education or training related to cancer treatment.

[1] Phase 1, Phase 2, and Phase 3 clinical trials are descriptions of different stages of clinical studies that are regulated by the FDA. Per 21 CFR 312.21, Phase 1 trials are designed to determine the metabolism and pharmacologic actions of drugs in humans, side effects and, to a limited degree, early indications of efficacy. Phase 1 studies involve small patient populations, very closely monitored. Phase 2 trials are designed to study side effects and risks of the drug in humans. Phase 2 trials involve several hundred patients/subjects. Phase 3 trials are designed to study the efficacy and to make an evaluation of overall safety of the drug in humans based on the scientific evidence. Phase 2 trials involve several thousand patients/subjects.

Board Staff presents the above-described points through a review of the medical care provided to seven patients who sought medical care by Respondent and Respondent's employees and through review of promotional statements made by Respondent, communications from the United States Food and Drug Administration ("FDA") and medical records related to those communications.

A. Specific Allegations: Violation of Standard of Care Patient A[2]

1. In September 2010, Patient A received a diagnosis of "sigmoid colon carcinoma metastatic to the liver." Imaging studies revealed erosions indicative of multiple liver lesions, and a colonoscopy revealed a polypoid mass consistent with high-grade dysplasia and suspicious for invasive adenocarcinoma.

2. Patient A declined a local physician's recommendation of a biopsy and the FOLFOX[3] chemotherapy regimen, including the medication Avastin[4].

3. Patient A sought treatment at the Respondent's clinic and met with Respondent on or about October 7, 2010.

4. Patient A sought treatment by Respondent with antineoplastons in part due to reading or viewing statements referenced in Allegation No. G(5 and 6) herein below.

5. At the time that Patient A first presented to Respondent and other doctors at the Burzynski Clinic, Patient A was not in a medical condition requiring emergency or intensive medical care.

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[2]Identification of all patients at issue in this Complaint will be provided by separate document under seal.
[3]Anti-cancer medication
[4]Anti-cancer medication

6. Prior to October 7, 2010, Patient A never had a histological or pathological confirmation that he had any kind of cancer. Respondent's failure to obtain a histological or pathological confirmation of cancer prior to initiating treatment before initiating treatment for Patient A with anti-cancer medications was a violation of the standard of care.

7. At the time of the initial meeting with Respondent, Patient A had not had a biopsy showing malignancy. Respondent did not order or recommend a biopsy before initiating treatment of Patient A. Respondent's order and/or recommendation of initiating anti-cancer treatment before obtaining a confirming biopsy or other relevant confirming test violated the standard of care.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D), 190.8(1)(G), and 190.8(1)(H); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

8. Respondent was one of Patient A's treating physicians throughout Patient A's treatment. Respondent directed all treatments of Patient A by physicians working at the Burzynski Clinic. Patient A's treatment was initiated at the Burzynski Clinic pursuant to Respondent's recommendations and direction.

9. At the time Patient A first met with Respondent and the other employees of the Burzynski Clinic, Respondent allowed Tolib Rakhmanov, a person who is not a licensed physician or health care provider in Texas or elsewhere in the United States of America, to represent to Patient A that Tolib Rakhmanov was a licensed medical doctor practicing medicine in Texas. Respondent and the other Burzynski Clinic employees under Respondent's supervision and control continued to represent to Patient A and Patient A's fiancée or to allow

them to believe that Tolib Rakhmanov was a licensed medical doctor practicing medicine in Texas throughout Patient A's treatment at the Burzynski Clinic.

10. Respondent and the other Burzynski Clinic employees under Respondent's supervision and control referred to Tolib Rakhmanov as "Dr. Rakhmanov" in Patient A's and Patient A's fiancée's presence. Respondent knew or reasonably knew that Tolib Rakhmanov signed documents, many of which were also signed by Patient A and Patient A's fiancée, in manners that identified Tolib Rakhmanov as a medical doctor. Patient A and Patient A's fiancée reasonably believed that Tolib Rakhmanov was a medical doctor licensed to practice medicine in the state of Texas. Respondent was responsible for the false, misleading and deceptive representation to Patient A and Patient A's fiancée that Tolib Rakhmanov was a medical doctor licensed to practice medicine in the state of Texas.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct that is likely to deceive or defraud the public, as provided by Section 164.053, or injure the public; (3) Section 164.053(a)(8) of the Act, failure supervise adequately the activities of those acting under the supervision of the physician; and (4) Section 164.053(a)(17) of the Act, directly or indirectly aiding and abetting the practice of medicine by a person, partnership, association, or corporation that is not licensed to practice medicine by the Board.

11. Tolib Rakhmanov, a person who is not a licensed physician or health care provider in Texas or elsewhere in the United States of America, performed medical tasks that constituted the practice of medicine in the state of Texas in the evaluation, diagnosis and treatment of Patient A, including the following:

a. Evaluation of Patient A's medical condition on about the following dates: October 7, 2010, October 11, 2010, October 12, 2010, October 13, 2010, October 14, 2010, October 15, 2010, October 18, 2010, October 19, 2010, October 21, 2010, October 22, 2010, October 25, 2010, January 6, 2011, February 3, 2011, February 17, 2011, March 9, 2011, June 29, 2011, August 29, 2011, August 30, 2011, September 1, 2011, September 2, 2011, September 6, 2011, September 20, 2011, October 13, 2011, October 21, 2011.

b. Diagnosis of Patient A's medical condition on or about the following dates: October 7, 2010, October 11, 2010, October 12, 2010, October 13, 2010,

October 14, 2010, October 15, 2010, October 18, 2010, October 19, 2010, October 21, 2010, October 22, 2010, October 25, 2010, January 6, 2011, February 3, 2011, February 17, 2011, March 9, 2011, June 29, 2011, August 29, 2011, August 30, 2011, September 1, 2011, September 2, 2011, September 6, 2011, September 20, 2011, October 13, 2011, October 21, 2011.

c. Making recommendations for treatment of Patient A's medical condition on or about the following dates: October 7, 2010, October 11, 2010, October 12, 2010, October 13, 2010, October 14, 2010, October 15, 2010, October 18, 2010, October 19, 2010, October 21, 2010, October 22, 2010, October 25, 2010, on or about January 6, 2011, on or about February 3, 2011, on or about February 17, 2011, on or about March 9, 2011, June 29, 2011, August 29, 2011, August 30, 2011, September 1, 2011, September 2, 2011, September 6, 2011, September 20, 2011, October 13, 2011, October 21, 2011.

d. Making decisions regarding the treatment of Patient A's medical condition on or about the following dates: October 7, 2010, October 11, 2010, October 12, 2010, October 13, 2010, October 14, 2010, October 15, 2010, October 18, 2010, October 19, 2010, October 21, 2010, October 22, 2010, October 25, 2010, January 6, 2011, February 3, 2011, February 17, 2011, March 9, 2011, June 29, 2011, August 29, 2011, August 30, 2011, September 1, 2011, September 2, 2011, September 6, 2011, September 20, 2011, October 13, 2011, October 21, 2011.

12. Respondent directed and/or reasonably knew and allowed Tolib Rakhmanov, a person who is not a licensed physician or health care provider in Texas or elsewhere in the United States of America, to perform medical tasks that constituted the practice of medicine in the state of Texas in the evaluation, diagnosis and treatment of Patient A. Respondent's direction, delegation and/or allowance of Tolib Rakhmanov's performance of medical tasks that constituted the practice of medicine in the state of Texas in the evaluation, diagnosis and treatment of Patient A constituted inadequate supervision and delegating a person to perform medical tasks for which that person was not appropriately trained and/or licensed.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); (4) Section 164.053(a)(8) of the Act, failure supervise adequately the activities of those acting under the supervision of the physician; (5) Section 164.053(a)(9) of the Act, delegation of professional medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not qualified by training, experience or licensure to perform the responsibility or acts. and

(6) Section 164.053(a)(17) of the Act, directly or indirectly aiding and abetting the practice of medicine by a person, partnership, association, or corporation that is not licensed to practice medicine by the Board.

13. After Respondent made recommendations and directions for Patient A's initial treatment by the Burzynski Clinic, Respondent continued to be Patient A's treating physician throughout Patient A's treatment by the Burzynski Clinic. Patient A was also treated by physicians who were working at the Burzynski Clinic and physicians were working in collaboration the Burzynski Clinic. All of these other physicians treated Patient A under Respondent's direction and control while Respondent was Patient A's treating physician.

14. Respondent initiated treatment of Patient A without adequately documenting Respondent's medical rationale and discussion with Patient A about Respondent's pathologic diagnosis. Respondent initiated treatment of Patient A without adequately documenting Respondent's analysis of genomic screening and discussion with Patient A about Respondent's genotypic and phenotypic diagnosis.

15. Respondent recommendation and/or direction to initiate anti-cancer treatment of Patient A without pathologic documentation of malignancy in Respondent's medical records for Patient A violated the standard of care and standards of adequate documentation.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D), 190.8(1)(G); 190.8(1)(H); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

16. Patient A had initially informed the Burzynski Clinic before he presented to the Burzynski Clinic that he wanted "antineoplaston" and FOLFOX/Vectibix therapies rather than classic or other chemotherapy treatments. At the time that Patient A presented to Respondent at the Burzynski Clinic on or about October 7, 2010, Patient A informed Respondent that Patient A

wanted "antineoplaston" and FOLFOX/Vectibix therapies rather than classic or other chemotherapy treatments.

17. Respondent and the other Burzynski Clinic employees under Respondent's supervision and control informed Patient A that he would be considered for chemotherapy in the Phase 3 clinical study of the FOLFOX/Vectibix[5] regime. At the time Respondent made this representation, Respondent failed to inform Patient A that Respondent was not able to and was not going to assist Patient A in obtaining access to being treated in this Phase 3 clinical study of the FOLFOX/Vectibix regime. Respondent's representation was false, misleading and deceptive.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct that is likely to deceive or defraud the public, as provided by Section 164.053, or injure the public; and (3) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

18. After assuring Patient A that he would obtain the "antineoplaston" and FOLFOX/Vectibix treatment he desired, Respondent and the employees of the Burzynski Clinic under his supervision and control directed Patient A to pay a large sum of money on retainer for anti-cancer therapy provided by the Burzynski Clinic.

19. After assuring Patient A that he would obtain the treatment he desired, and after Patient A paid a large sum of money on retainer for anti-cancer therapy by the Burzynski Clinic, Respondent recommended and directed treatments for Patient A that did not include "antineoplaston" and FOLFOX/Vectibix therapies. Respondent recommended and directed treatments with these other substances without adequately explaining to Patient A the difference in safety and efficacy between the therapy requested by Patient A and the therapy provided by Respondent and the employees of the Burzynski Clinic under his supervision and control.

Violation

[5]Anti-cancer medication

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C), 190.8(1)(H), and 190.8(1)(I); and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

20. Respondent recommended and directed that Patient A start treatment with phenylbutyrate[6] and a partially FOLFOX equivalent regimen (oral Xeloda[7] and intravenous Avastin).

21. Respondent's recommendations and directions for treatment of patients, including the patients in this contested case, by the Burzynski Clinic and by the Burzynski Research Institute and the Burzynski Research Institute – Institutional Review Board ("BRI-IRB") controlled the treatments provided to all patients by the Burzynski Clinic and by the Burzynski Research Institute and the BRI-IRB. Respondent's recommendations and directions for treatment of patients, including the patients in this contested case, by the Burzynski Clinic and by the Burzynski Research Institute and the BRI-IRB overruled any independent decision-making of the employees of the Burzynski Clinic, the Burzynski Research Institute and the BRI-IRB.

22. Respondent recommended and directed that Patient A start various other substances for treatment, including:

a. Votrient[8]
b. Oxaliplatin[9]
c. Avastin
d. Xeloda[10]
e. Decadron[11]
f. Xgeva[12]

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[6] Anti-cancer medication
[7] Anti-cancer medication
[8] Anti-cancer medication
[9] Anti-cancer medication
[10] Anti-cancer medication
[11] Anti-cancer medication

23. Patient A showed an improvement during the initial eight months after treatment with oxaliplatin, Avastin, Xeloda and phenylbutyrate under the direction and control of Respondent. In late April 2011, imaging of the affected area of the brain tissue revealed that the affected area was shrinking. In late April 2011, Respondent recommended and directed that the treatment be changed by eliminating some of the medications being used for Patient A by the Burzynski Clinic. In mid-May 2011, imaging of the affected area of the brain tissue revealed that the affected area had resumed growing larger. Respondent failed to have and failed to document an adequate medical rationale for a change of therapy when Patient A's symptoms related to cancer were improving after late January 2011 and prior to late April 2011. Respondent also failed to adequately supervise

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D); (4) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; (5) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician; and (6) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

24. Patient A's initial improvement was not sustained after late April 2011, and Patient A's medical condition deteriorated as the tumor growth and spread worsened. Respondent's evaluation, diagnosis and treatment of Patient A ended at the end of October 2011.

25. The Burzynski Clinic, under Respondent's direction and control, billed Patient B and Patient B's healthcare insurance carrier for services and charges that were medically unnecessary and not adequately supported by documentation including the following:

a. October 7, 2010
Dr. Valladares/Office Consultation $1,000.00

[12] Anti-cancer medication

	Her-2/Neu	$350.00
	Immunoflourescent Study	$350.00
	Molecule Isolate Nucleic	$142.00
	VEG F Vascular Endothelial	$400.00
	Dr. Valladares/Prolonged Ser. W/O Contact	$350.00
	Genetic Examination	$141.00
	EGFR Epidermal Growth Factor	$400.0
	Dr. Valladares/Prolonged Ser. W/O Contact	$150.00
	Dr. Valladares/Prolonged Phys. Svc In Office	$250.00
b.	October 11, 2010	
	Measure Blood Oxygen Level	$35.00
	Sodium Phenylbutyrate 500 mg	$60.00
	Sodium Phenylbutyrate 500 mg	$60.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
c.	October 12, 2010	
	Sodium Phenylbutyrate 500 mg	$120.00
	Measure Blood Oxygen Level	$35.00
	Sodium Phenylbutyrate 500 mg	$120.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
	Add Supplies – A 10	$1,080.00
d.	October 13, 2010	
	Special Service Stat	$15.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
	MG Magnesium	$50.00
	Lipid Panel	$50.00
	Sodium Phenylbutyrate 500 mg	$180.00
	Molecular Diagnostics	$90.00
	Genetic Examination	$75.00
	LD Lactate Dehydrogenase	$25.00
	Molecule Isolate Nucleic	$75.00
	Molecule Nucleic Ampli, Each	$80.00
	Sodium Phenylbutyrate 500 mg	$180.00
	Nucleic Acid, High Resolute	$140.00
	UA Urinalysis, Non-Auto W/	$25.00
	Molecule Mutation Identify	$140.00
	Measure Blood Oxygen Level	$35.00
	Sodium Phenylbutyrate 500 mg	$240.00
	Sodium Phenylbutyrate 500 mg	$240.00
e.	October 14, 2010	
	Measure Blood Oxygen Level	$35.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
f.	October 15, 2010	
	Therapeutic IV Push, Each A	$100.00
	Sodium Phenylbutyrate 500 mg	$300.00

	Measure Blood Oxygen Level	$35.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
	Intravenous push, Single Or	$125.00
	Avastin 10 mg	$2,420.20
	Xeloda Oral 500 mg	$1,887.73
g.	October 16, 2010	
	Sodium Phenylbutyrate 500 mg	$360.00
h.	October 17, 2010	
	Sodium Phenylbutyrate 500 mg	$360.00
i.	October 18, 2010	
	Lipid Panel	$50.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
	Sodium Phenylbutyrate 500 mg	$360.00
	LD Lactate Dehydrogenase	$25.00
	Measure Blood Oxygen Level	$35.00
	Special Service Stat	$15.00
j.	October 19, 2010	
	Sodium Phenylbutyrate 500 mg	$360.00
	Measure Blood Oxygen Level	$35.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
k.	October 20, 2010	
	Sodium Phenylbutyrate 500 mg	$360.00
l.	October 21, 2010	
	UA Urinalysis, Non-Auto W/	$25.00
	Sodium Phenylbutyrate 500 mg	$360.00
	Measure Blood Oxygen Level	$35.00
	LD Lactate Dehydrogenase	$25.00
	Lipid Panel	$50.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
m.	October 22, 2010	
	Lithium batteries, AA	$10.22
	Intravenous Push, Single Or	$125.00
	Avastin, 10 mg	$3,630.36
	Sodium Phenylbutyrate 500 mg	$360.00
	Measure Blood Oxygen Level	$35.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
n.	October 23, 2010	
	Sodium Phenylbutyrate 500 mg	$360.00
o.	October 24, 2010	
	Sodium Phenylbutyrate 500 mg	$360.00
p.	October 25, 2010	
	Monthly Case Management	$4,500.00
	Measure Blood Oxygen Level	$35.00
	Dr. Valladares/Office/Outpatient Visit	$125.00

	Sodium Phenylbutyrate 500 mg	$360.00
q.	November 8, 2010	
	Add Supplies – A10	$1,080.00
r.	November 18, 2010	
	Monthly Case Management	$4,500.00
s.	December 6, 2010	
	Monthly Case Management	$4,500.00
t.	December 30, 2010	
	Monthly Case Management	$4,500.00
u.	January 24, 2011	
	Add Supplies – A10	$1,080.00
v.	February 8, 2011	
	Monthly Case Management	$2,250.00
x.	March 18, 2011	
	Monthly Case Management	$2,250.00
y.	March 24, 2011	
	Monthly Case Management	$2,250.00
z.	April 21, 2011	
	Monthly Case Management	$2,250.00
aa.	June 10, 2011	
	Monthly Case Management	$2,250.00
bb.	August 3, 2011	
	Monthly Case Management	$2,250.00
cc.	August 29, 2011	
	Lipid Panel	$50.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
	Measure Blood Oxygen Level	$35.00
dd.	August 30, 2011	
	Afinitor 10 mg	$799.65
	Measure Blood Oxygen Level	$35.00
	Dr. Valladares/Office/Outpatient Visit	$100.00
ee.	September 1, 2011	
	Sodium Phenylbutyrate 500 mg	$3,600.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
	Chemo, IV Infusion 1 hr.	$198.00
	Parenteral infusion pump portable	$100.00
	Famotidine 20 mg	$100.00
	Therapeutic IV Push, Each A	$100.00
	Intravenous Push, Single Or	$125.00
	Camptosar/Irinotecan 20 mg	$610.24
	Measure Blood Oxygen Level	$35.00
	Special Service Stat	$15.00
	Lithium Batteries AA	$10.22
ff.	September 2, 2011	

	Dr. Valladares/Office/Outpatient Visit	$125.00
	Measure Blood Oxygen Level	$35.00
gg.	September 6, 2011	
	Lipid Panel	$50.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
	LD Lactate Dehydrogenase	$25.00
	Measure Blood Oxygen Level	$35.00
	Special Service Stat	$15.00
	MG Magnesium	$50.00
hh.	September 7, 2011	
	Votrient 200 mg	$669.34
ii.	September 8, 2011	
	Afinitor 100 mg	$12,494.50
	Votrient 200 mg	$4,016.04
	Measure Blood Oxygen Level	$35.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
jj.	September 11, 2011	
	Sodium Phenylbutyrate 500 mg	$3,600.00
kk.	October 4, 2011	
	Sodium Phenylbutyrate 500 mg	$3,600.00
ll.	October 21, 2011	
	IV Infusion Each Add Hour	$150.00
	Special Service Stat	$15.00
	Parenteral infuse pump portab	$100.00
	Lithium Batteries AA	$10.22
	Dr. Valladares/Office/Outpatient Visit	$125.00
	Measure Blood Oxygen Level	$35.00
	IV Infusion Therapy	$198.00
	Patenteral Nutrition	$175.00
mm.	October 22, 2011	
	Dr. Valladares/Office/Outpatient Visit	$75.00
	IV Infusion Therapy	$198.00
	Patenteral Nutrition	$175.00
	Measure Blood Oxygen Level	$35.00
	Ammonia Serum Panel	$85.00
	Lithium Batteries AA	$10.22

26. Many of the improper charges for evaluation, diagnosis and treatment of Patient A by the Burzynski Clinic were done at the direction and control of Respondent, and were for medically unnecessary services. Many of the improper charges for evaluation, diagnosis and treatment of Patient A by the Burzynski Clinic under the direction and control of Respondent

were not adequately supported by documentation. These improper charges constituted violations of the Act and Board Rules.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); (4) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; (5) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper; and (6) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

27. Respondent inadequately supervised the activities of Burzynski Clinic employees who were evaluating and treating Patient A. Respondent's inadequate supervision included failure to document his review of documents related to evaluation, diagnosis and treatment of Patient A.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

28. Respondent delegated professional medical responsibility or acts to employees of the Burzynski Clinic regarding the evaluation and treatment of Patient A when Respondent knew or had reason to know that those employees were not qualified by training, experience or licensure to perform the responsibility or acts. Those acts included the following:

a. Evaluation of Patient A's medical condition on about the following dates: October 7, 2010, October 11, 2010, October 12, 2010, October 13, 2010, October 14, 2010, October 15, 2010, October 18, 2010, October 19, 2010, October 21, 2010, October 22, 2010, October 25, 2010, January 6, 2011, February 3, 2011, February 17, 2011, March 9, 2011, June 29, 2011, August 29, 2011, August 30,

2011, September 1, 2011, September 2, 2011, September 6, 2011, September 20, 2011, October 13, 2011, October 21, 2011.

b. Diagnosis of Patient A's medical condition on or about the following dates: October 7, 2010, October 11, 2010, October 12, 2010, October 13, 2010, October 14, 2010, October 15, 2010, October 18, 2010, October 19, 2010, October 21, 2010, October 22, 2010, October 25, 2010, January 6, 2011, February 3, 2011, February 17, 2011, March 9, 2011, June 29, 2011, August 29, 2011, August 30, 2011, September 1, 2011, September 2, 2011, September 6, 2011, September 20, 2011, October 13, 2011, October 21, 2011.

c. Making recommendations for treatment of Patient A's medical condition on or about the following dates: October 7, 2010, October 11, 2010, October 12, 2010, October 13, 2010, October 14, 2010, October 15, 2010, October 18, 2010, October 19, 2010, October 21, 2010, October 22, 2010, October 25, 2010, on or about January 6, 2011, on or about February 3, 2011, on or about February 17, 2011, on or about March 9, 2011, June 29, 2011, August 29, 2011, August 30, 2011, September 1, 2011, September 2, 2011, September 6, 2011, September 20, 2011, October 13, 2011, October 21, 2011.

d. Making decisions regarding the treatment of Patient A's medical condition on or about the following dates: October 7, 2010, October 11, 2010, October 12, 2010, October 13, 2010, October 14, 2010, October 15, 2010, October 18, 2010, October 19, 2010, October 21, 2010, October 22, 2010, October 25, 2010, January 6, 2011, February 3, 2011, February 17, 2011, March 9, 2011, June 29, 2011, August 29, 2011, August 30, 2011, September 1, 2011, September 2, 2011, September 6, 2011, September 20, 2011, October 13, 2011, October 21, 2011.

29. Respondent's delegation of professional medical responsibility or acts to employees of the Burzynski Clinic, regarding the evaluation and treatment of Patient A, when Respondent knew or had reason to know that those employees were not qualified by training, experience or licensure to perform the responsibility or acts violated several provisions of the Act and Board Rules.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); and (4) Section 164.053(a)(9) of the Act, delegation of professional medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not qualified by training, experience or licensure to perform the responsibility or acts.

30. Respondent's recommendation and/or direction for the treatment of Patient A with various substances referenced in Allegation No. A.22 above violated the standard of care.

a. Physical examination.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate physical examination of Patient A at the time that Respondent recommended and/or directed anti-cancer treatment for Patient A. These failures to perform an adequate physical examination included:

a. After the initial office visit physical examination in October 2010 during the time period of office visits in October 2010.
b. At the time that Patient A returned to the Burzynski clinic in August 2011.
c. During the nine month period between October 2010 and when Patient A returned to the Burzynski clinic in August 2011.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standards of adequate documentation by failure to document performance of an adequate physical examination of Patient A at the time that Respondent recommended and/or directed anti-cancer treatment for Patient A.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D); (4) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (5) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

b. Mental status examination.

(1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate physical examination of Patient A at the time that Respondent recommended and/or

directed anti-cancer treatment for Patient A. These failures to perform an adequate mental status examination included:

a. After the initial office visit physical examination in October 2010 during the time period of office visits in October 2010.
b. At the time that Patient A returned to the Burzynski clinic in August 2011.
c. During the nine month period between October 2010 and when Patient A returned to the Burzynski clinic in August 2011.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate mental status examination at the time that Respondent recommended and/or directed anti-cancer treatment for Patient A. Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate mental status examination after initiating recommended anti-cancer treatments for Patient A. These failures to perform the elements of an adequate mental status examination included failure to determine:

a. the patient's ability to identify themselves;
b. the patient's awareness of their surroundings;
c. whether the patient is aware of what they are being seen for;
d. the patient's ability to make decisions for themselves;
e. the patient's ability to understand the directions for taking the medications;
f. the patient's awareness of the risks of the medications;
g. patient's frame of mind and general psychiatric condition, such as anxiety or depression, if any.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document a mental status examination at the time that Respondent recommended and/or directed anti-cancer treatment for Patient A.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); and 190.8(1)(C); (4) Section

164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (5) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

c. Treatment plan.

1) The inadequate treatment plan documented by Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision for Patient A at the time that Respondent recommended and/or directed anti-cancer treatment for Patient A violated the standard of care. Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision failed to include the following elements of a treatment plan that are required by the standard of care:

a. Objectives to measure treatment effectiveness, including a method for determining effectiveness of polypharmacy, when more than one substance is used to treat a patient during the same time period;
b. Objectives for alleviation of symptoms;
c. Monitoring of objectives of treatment effectiveness;
d. Monitoring of alleviation of symptoms;
e. Monitoring of side effects of treatment; and
f. Dosages and instructions for treatment medications.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document an adequate treatment plan at the time that Respondent recommended and/or directed anti-cancer treatment for Patient A.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); and 190.8(1)(C); (4) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (5) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

d. Over-all medical rationale.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to have an adequate medical rationale for evaluation, diagnosis and treatment at the time of Respondent recommendations and/or direction of anti-cancer therapy for Patient A.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document an adequate medical rationale for evaluation, diagnosis and treatment at the time of Respondent's recommendations and/or direction of anti-cancer therapy for Patient A.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(A); and 190.8(1)(C); (4) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (5) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

e. Informed consent.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to adequately discuss about the risks and benefits of the treatment with Patient A at the time of Respondent recommendations and/or direction of anti-cancer therapy for Patient A.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standards of adequate documentation by failure to document an adequate discussion about the risks and benefits of the treatment with

Patient A at the time of Respondent's recommendations and/or direction of anti-cancer therapy for Patient A.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (4) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (5) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

f. Discussion of treatment alternatives.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to adequately discuss alternative anti-cancer treatments with Patient A at the time of Respondent recommendations and/or direction of anti-cancer therapy for Patient A.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document alternative treatments discussed with Patient A at the time of Respondent's recommendations and/or direction of anti-cancer therapy for Patient A.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D), 190.8(1)(H); (4) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (5) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

31. Respondent had an ownership interest in the pharmacy that dispensed phenylbutyrate and other drugs provided by the pharmacy owned by Respondent. Respondent's failure to disclose this ownership interest to Patient A violated the Act and Board Rules.

Violation

(1) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility.

32. Respondent billed multiple charges to the patient for which there is no adequate description of the service or product in the medical record. These charges are listed in Allegation A.25 above. Respondent also, therefore, billed for these services and/or products improperly.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); (4) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; and (5) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper; and (6) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

33. Respondent directed the unnecessary measurement of Patient A's oxygen saturation. Patient A had no significant pulmonary disease, and the medial records are without justification for this testing. Respondent also, therefore, billed for these services and/or products improperly.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); (4) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; (5)

Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper. and (6) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

34. Respondent directed the unnecessary and costly laboratory testing for measures that are without demonstrable benefit to Patient A, including, at the initial visit, an echocardiogram, an assay of plasma VEGF, serum EGFR, and her-2. Respondent also, therefore, billed for these services and/or products improperly.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); (3) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; (4) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper; and (5) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

35. Respondent had an ownership interest in the laboratory that performed the tests that Respondent directed. Respondent did not disclose this ownership interest to Patient A.

Violation

(1) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility.

36. Respondent failed to adequately inform Patient A of the risks and benefits of the therapies that Respondent recommended and/or directed for Patient A and to document that Patient A had been adequately informed.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as

further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (4) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (5) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

37. Failure to adhere to and violation of the standard of care when recommending and/or directing anti-cancer treatment is non-therapeutic treatment.

38. Providing anti-cancer treatments for which the benefits have not been proven by Phase 3 studies to outweigh the known risks of such treatments when recommending and/or directing anti-cancer treatment is non-therapeutic treatment, unless such treatment is provided pursuant to an appropriate, approved and properly conducted clinical study in compliance with federal law and regulations.

39. Respondent's recommendations and/or directions for the treatment of Patient A were non-therapeutic treatment. Several of Respondent's recommendations and/or direction for the treatment of Patient A were not proven by Phase 3 studies to outweigh the know risks of such treatments and not provided pursuant to an appropriate, approved and properly conducted clinical study in compliance with federal law and regulations.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

40. Respondent and other health care providers under Respondent's direction and control treated Patient A without regard to the potential combined toxicities of drugs used pursuant to Respondent's recommendations and directions. Respondent and other health care providers under Respondent's direction and control referenced the case reports of other

physicians not associated with the Burzynski Clinic as support for combined use of the drugs recommended and administered to Patient A. In those referenced case reports of physicians not associated with the Burzynski Clinic, however, those drugs were only used individually or in other combinations besides the combinations of drugs used for Patient A by Respondent and other health care providers under Respondent's direction and control. In this regard, Respondent and other health care providers under Respondent's direction and control violated the standard of care for reasons including:

a. Patient A suffered considerable toxicity affects.
b. Respondent violated the standard of care by failing to have an adequate medical rationale for this simultaneous use of these agents in anti-cancer therapy.
c. Respondent violated standards of adequate documentation by failing to document an adequate medical rationale for this simultaneous use of these agents in anti-cancer therapy.
d. Respondent also failed to adequately inform Patient A of this increased risk.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

41. An adequate medical rationale for anti-cancer treatments, including classic chemotherapy, medications used for purposes not approved by the federal Food and Drug Administration (FDA) and investigational new drugs requires:

(a) review of prior history and records of prior treatment and related conditions;
(b) adequate physical examination;
(c) adequate mental status examination;
(d) treatment plan, including description of the therapy (including amounts and dosages), periodic review, measurable objectives and monitoring of progress toward objectives;
(e) medical rationale;
(f) informed consent, including a discussion with Patient A about the risks and benefits of the proposed treatment;

(g) discussion of alternatives to the treatment.

42. The standards of adequate documentation for anti-cancer treatments, including classic chemotherapy, medications used for purposes not approved by the federal Food and Drug Administration (FDA) and investigational new drugs requires adequate documentation of:

(a) review of prior history and records of prior treatment and related conditions;
(b) adequate physical examination;
(c) mental status examination;
(d) treatment plan, including description of the therapy (including amounts and dosages), periodic review, measurable objectives and monitoring of progress toward objectives;
(e) medical rationale;
(f) informed consent, including a discussion with Patient A about the risks and benefits of the proposed treatment;
(g) discussion of alternatives to the treatment.

B. Specific Allegations: Violation of Standard of Care Patient B

1. In December 2010, Patient B received a diagnosis of a brain tumor. The brain tumor was removed surgically by craniotomy, followed by imaging that showed the complete removal of the tumor. Post-surgery radiation and chemotherapy treatment was recommended, but Patient B sought alternative treatment from Respondent at the Burzynski Clinic.

2. Patient B sought treatment at the Burzynski Clinic and met with Respondent on or about February 1, 2011.

3. After the post-craniotomy imaging and prior to February 1, 2011, Patient B did not have a histological or pathological confirmation that he continued to have any kind of cancer. Respondent's failure to obtain a histological or pathological confirmation of cancer prior to initiating treatment before initiating treatment with anti-cancer medications was a violation of the standard of care.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D),

190.8(1)(G), and 190.8(1)(H); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

4. At the time that Patient B first presented to Respondent and other doctors at the Burzynski Clinic, Patient B was not in a medical condition requiring emergency or intensive medical care.

5. Patient B sought treatment by Respondent with antineoplastons in part due to reading or viewing statements referenced in Allegation No. G(5 and 6) herein below.

6. At the time of the initial meeting with Respondent, Patient B had not had a biopsy after the craniotomy showing malignancy. Respondent did not order or recommend a biopsy before initiating treatment of Patient B. Respondent's order and/or recommendation of initiating anti-cancer treatment before obtaining a confirming biopsy or other relevant confirming test.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D), 190.8(1)(G), and 190.8(1)(H); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

7. Respondent recommendation and/or direction to initiate anti-cancer treatment of Patient B without pathologic documentation of malignancy in Respondent's medical records for Patient B violated the standard of care and standards of adequate documentation.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D), 190.8(1)(G); 190.8(1)(H); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a

manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

8. Respondent initiated treatment of Patient B without adequately documenting Respondent's medical rationale and discussion with Patient B about Respondent's pathologic diagnosis. Respondent initiated treatment of Patient B without adequately documenting Respondent's analysis of genomic screening and discussion with Patient B about Respondent's genotypic and phenotypic diagnosis.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; and (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C).

9. Respondent was one of Patient B's treating physicians throughout Patient B's treatment directed by physicians working at the Burzynski Clinic. Patient B's treatment was initiated at the Burzynski Clinic pursuant to Respondent's recommendations and direction.

10. At the time the Patient B first met with Respondent and the other employees of the Burzynski Clinic, Respondent allowed Tolib Rakhmanov and Larisa Tikhomirova, persons who are not licensed physicians or health care providers in Texas or elsewhere in the United States of America, to represent to Patient B that Tolib Rakhmanov and Larisa Tikhomirova were licensed medical doctors practicing medicine in Texas. Respondent continued to allow Patient B and Patient B's wife to believe that Tolib Rakhmanov and Larisa Tikhomirova were licensed medical doctors practicing medicine in Texas throughout Patient B's treatment at the Burzynski Clinic.

11. Respondent and the other Burzynski Clinic employees under Respondent's supervision and control referred to Tolib Rakhmanov as "Doctor Rakhmanov" and Larisa Tikhomirova as "Doctor Tikhomirova" in Patient B's, Patient B's wife's and Patient B's personal physician, Dr. Demetri Brandt's presence and in writing. Respondent reasonably knew that Tolib Rakhmanov and Larisa Tikhomirova signed documents, many of which were also

signed by Patient B and Patient B's wife, in manners that identified themselves as medical doctors. Patient B and Patient B's wife reasonably believed that Tolib Rakhmanov and Larisa Tikhomirova were medical doctors licensed to practice medicine in the state of Texas. Respondent was responsible for the false, misleading and deceptive representation to Patient B, Patient B's wife and Patient B's personal physician, Dr. Brandt, that Tolib Rakhmanov and Larisa Tikhomirova were medical doctors licensed to practice medicine in the state of Texas.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct that is likely to deceive or defraud the public, as provided by Section 164.053, or injure the public; and (3) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

12. Prior to Patient B's arrival at the Burzynski Clinic on or about February 1, 2011, Respondent and/or employees under his direction and control failed to inform Patient B about the FDA-approved criteria for treatment with antineoplastons in one of Respondent's sponsored clinical studies.

13. Respondent and/or employees under his direction and control informed Patient B that he would be considered for treatment with antineoplastons in one of Respondent's sponsored clinical studies. At the time Respondent and/or employees under his direction and control made this representation, Respondent and/or employees under his direction and control failed to inform Patient B that Respondent was not going to assist Patient B in obtaining access to being treated in an FDA-approved clinical study. Therefore, Respondent's representation was false, misleading and deceptive. Respondent and/or employees under his direction and control made additional representations to United States Customs agents that Patient B was being treated with antineoplastons in an FDA-approved clinical study.

Violation

Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct that is likely to deceive or defraud the public, as provided by Section 164.053, or injure the public.

14. Respondent and/or employees under his direction and control made additional representations to United States Customs agents that Patient B was being treated with antineoplastons in an FDA-approved clinical study.

Violation

Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct that is likely to deceive or defraud the public, as provided by Section 164.053, or injure the public.

15. Tolib Rakhmanov and Larisa Tikhomirova, persons who are not licensed physicians or health care providers in Texas or elsewhere in the United States of America, performed the following medical tasks that constituted the practice of medicine in the state of Texas in the evaluation, diagnosis and treatment of Patient B:

a. Evaluation of Patient B's medical condition on or about February 7, 2011, February 8, 2011, February 9, 2011, February 10, 2011, February 11, 2011, February 12, 2011, February 14, 2011, February 15, 2011, February 16, 2011, February 17, 2011, February 18, 2011, February 21, 2011, February 22, 2011, February 23, 2011, February 24, 2011, February 25, 2011, February 28, 2011, March 1, 2011, March 2, 2011, March 3, 2011, March 4, 2011, March 21, 2011, May 24, 2011, June 16, 2011, June 17, 2011, July 1, 2011, July 5, 2011, July 6, 2011, July 7, 2011, August 19, 2011, and August 29, 2011.

b. Diagnosis of Patient B's medical condition on or about February 7, 2011, February 8, 2011, February 9, 2011, February 10, 2011, February 11, 2011, February 12, 2011, February 14, 2011, February 15, 2011, February 16, 2011, February 17, 2011, February 18, 2011, February 21, 2011, February 22, 2011, February 23, 2011, February 24, 2011, February 25, 2011, February 28, 2011, March 1, 2011, March 2, 2011, March 3, 2011, March 4, 2011, March 21, 2011, May 24, 2011, June 16, 2011, June 17, 2011, July 1, 2011, July 5, 2011, July 6, 2011, July 7, 2011, August 19, 2011, and August 29, 2011.

c. Making recommendations for treatment of Patient B's medical condition on or about February 7, 2011, February 8, 2011, February 9, 2011, February 10, 2011, February 11, 2011, February 12, 2011, February 14, 2011, February 15, 2011, February 16, 2011, February 17, 2011, February 18, 2011, February 21, 2011, February 22, 2011, February 23, 2011, February 24, 2011, February 25, 2011, February 28, 2011, March 1, 2011, March 2, 2011, March 3, 2011, March 4, 2011, March 21, 2011, May 24, 2011, June 16, 2011, June 17, 2011, July 1, 2011, July 5, 2011, July 6, 2011, July 7, 2011, August 19, 2011, and August 29, 2011.

d. Making decisions regarding the treatment of Patient B's medical condition on or about February 7, 2011, February 8, 2011, February 9, 2011, February 10,

2011, February 11, 2011, February 12, 2011, February 14, 2011, February 15, 2011, February 16, 2011, February 17, 2011, February 18, 2011, February 21, 2011, February 22, 2011, February 23, 2011, February 24, 2011, February 25, 2011, February 28, 2011, March 1, 2011, March 2, 2011, March 3, 2011, March 4, 2011, March 21, 2011, May 24, 2011, June 16, 2011, June 17, 2011, July 1, 2011, July 5, 2011, July 6, 2011, July 7, 2011, August 19, 2011, and August 29, 2011.

16. Respondent directed and/or reasonably knew of and allowed Tolib Rakhmanov and Larisa Tikhomirova, persons who are not licensed physicians or health care providers in Texas or elsewhere in the United States of America, to perform medical tasks that constituted the practice of medicine in the state of Texas in the evaluation, diagnosis and treatment of Patient B.

17. Respondent's direction, delegation and/or allowance of Tolib Rakhmanov's and Larisa Tikhomirova's performance of medical tasks that constituted the practice of medicine in the state of Texas in the evaluation, diagnosis and treatment of Patient B constituted inadequate supervision and delegating a person to perform medical tasks for which that person was not appropriately trained and/or licensed.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); and (4) Section 164.053(a)(9) of the Act, delegation of professional medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not qualified by training, experience or licensure to perform the responsibility or acts.

18. After Respondent made recommendations for Patient B's treatment, Respondent continued to be Patient B's treating physician throughout Patient B's treatment by the Burzynski Clinic. Patient B was also treated by physicians who were working at the Burzynski Clinic and physicians were working in collaboration the Burzynski Clinic. All of these other physicians treated Patient B under Respondent's direction and control while Respondent was Patient B's treating physician.

19. Patient B had initially informed the Burzynski Clinic that Patient B wanted "antineoplaston" therapy rather than classic or other chemotherapy treatments. At the time that Patient B presented to Respondent at the Burzynski Clinic on or about February 1, 2011, Patient B informed Respondent that Patient B wanted "antineoplaston" therapy rather than classic or other chemotherapy treatments.

20. After assuring Patient B that he would obtain the treatment he desired, Respondent and the employees of the Burzynski Clinic under his supervision and control directed Patient B to pay a large sum of money on retainer for the anti-cancer therapy by the Burzynski Clinic.

21. After assuring Patient B that he would obtain the treatment he desired, and after Patient B paid a large sum of money on retainer for anti-cancer therapy by the Burzynski Clinic, Respondent recommended and directed treatments for Patient B that did not include "antineoplaston" therapy. Respondent recommended and directed treatments with these other substances without adequately explaining to Patient B the difference in safety and efficacy between the therapy requested by Patient B and the therapy provided by Respondent and the employees of the Burzynski Clinic under his supervision and control.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C), 190.8(1)(H), and 190.8(1)(I); and (3) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

22. Beginning on or about February 1, 2011, Respondent recommended and directed that Patient B start treatment with phenylbutyrate and other substances. On or about March 17, 2011, an MRI of Patient B's brain revealed moderate decrease in the size of the brain lesion. On or about March 21, 2011, Respondent first recommended and directed that Patient B start treatment with antineoplastons. Respondent recommended and/or directed that Patient B start treatment with the following substances:

a. phenylbutyrate
b. Votrient
c. Avastin
d. Tarceva[13]
e. Afinitor[14]
f. Sprycel[15]
g. Nexavar[16]
h. Zolinza[17]
i. Antineoplastons

23. Patient B showed an improvement during one month after treatment with Votrient, Avastin and phenylbutyrate began under the direction and control of Respondent began. After early March 2011, Respondent recommended and directed that Patient B stop taking phenylbutryrate and start taking antineoplastons. After early March 2011, Patient B's initial improvement was not sustained, and Patient B's medical condition and tumor growth and spread worsened. Respondent failed to have and failed to document an adequate medical rationale for a change of therapy when Patient B's symptom was improving in early March 2011.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D); (4) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (5) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

24. Respondent's evaluation, diagnosis and treatment of Patient B ceased at the end of September 2011.

[13] Anti-cancer medication
[14] Anti-cancer medication
[15] Anti-cancer medication
[16] Anti-cancer medication
[17] Anti-cancer medication

25. The Burzynski Clinic, under Respondent's direction and control, billed Patient B and Patient B's healthcare insurance carrier for services and charges that were medically unnecessary and not adequately supported by documentation including the following:

a.	February 7, 2011	
	VEG F Vascular Endothelial	$400.00
	Molecule Mutation Identify	$200.00
	Genetic Examination	$40.00
	EGFR Epidermal Growth Factor	$400.00
	Her-2/Neu	$350.00
	Add Supplies – A10	$1,080.00
	Addtl 30 min – Prolonged Ph	$100.00
	Prolonged Phys Svc in ofc	$250.00
	Molecular Diagnostics	40.00
	Prolonged Serv. w/o contact	$150.00
	Prolonged Serv. w/o contact	$350.00
	Dr. Valladares/Office Consultation	$1,000.00
b.	February 8, 2011	
	Sodium Phenylbutyrate 500 mg	$60.00
	Dexamethasone Oral 0.25 mg	$34.80
	Dr. Valladares/Office/Outpatient Visit	$125.00
	Measure Blood Oxygen Level	$35.00
c.	February 9, 2011	
	Measure Blood Oxygen Level	$35.00
	Sodium Phenylbutyrate 500 mg	$120.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
d.	February 10, 2011	
	Sodium Phenylbutyrate 500 mg	$240.00
	Measure Blood Oxygen Level	$35.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
e.	February 11, 2011	
	MG Magnesium	$50.00
	Sodium Phenylbutyrate 500 mg	$2,160.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
	LD Lactate Dehydrogenase	$25.00
	Lipid Panel	$50.00
	Measure Blood Oxygen Level	$35.00
f.	February 14, 2011	
	Dr. Valladares/Office/Outpatient Visit	$125.00
	Measure Blood Oxygen Level	$35.00
g.	February 15, 2011	
	Votrient 200 mg	$6,030.00
	Measure Blood Oxygen Level	$35.00

	Dr. Valladares/Office/Outpatient Visit	$125.00
h.	February 16, 2011	
	Votrient 200 mg	$6,030.00
	Measure Blood Oxygen Level	$35.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
i.	February 17, 2011	
	Intravenous push, Single Or	$125.00
	Lipid Panel	$50.00
	Lithium batteries, AA	$10.22
	UA Urinalysis, Non-Auto W/	$25.00
	Therapeutic IV Push, Each A	$100.00
	Chemo, IV infusion 1 hr	$198.00
	MG Magnesium	$50.00
	LD Lactate Dehydrogenase	$25.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
	Avastin 10 mg	$1,237.34
	Measure Blood Oxygen Level	$35.00
j.	February 18, 2011	
	Sodium Phenylbutyrate 500 mg	$1,440.00
	Measure Blood Oxygen Level	$35.00
	Dr. Weaver/Office/Outpatient Visit	$125.00
k.	February 21, 2011	
	Measure Blood Oxygen Level	$35.00
	Mg Magnesium	$50.00
	Intravenous push, Single Or	$125.00
	Dr. Weaver/Office/Outpatient Visit	$125.00
	Lipid Panel	$50.00
	UA Urinalysis, Non-Auto W/	$25.00
	Chemo, IV infusion 1 hr	$198.00
	Avastin 10 mg	$4,949.34
	LD Lactate Dehydrogenase	$25.00
	Lithium batteries, AA	$10.22
	Parental infuse pump portable	$100.00
l.	February 22, 2011	
	Dr. Valladares/Office/Outpatient Visit	$125.00
	Sodium Phenylbutyrate 500 mg	$1,080.00
	Measure Blood Oxygen Level	$35.00
m.	February 23, 2011	
	Measure Blood Oxygen Level	$35.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
n.	February 24, 2011	
	Add supplies – BLF	$600.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
	Measure Blood Oxygen Level	$35.00

	Mg Magnesium	$50.00
	LD Lactate Dehydrogenase	$25.00
	Lipid Panel	$50.00
o.	February 25, 2011	
	Sodium Phenylbutyrate 500 mg	$1,440.00
	Measure Blood Oxygen Level	$35.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
p.	February 28, 2011	
	Measure Blood Oxygen Level	$35.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
	UA Urinalysis, Non-Auto W/	$25.00
	MG Magnesium	$50.00
	Lipid Panel	$50.00
	LD Lactate Dehydrogenase	$25.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
	Group Health Education	$60.00
q.	March 1, 2011	
	Sodium Phenylbutyrate 500 mg	$1,440.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
	Measure Blood Oxygen Level	$35.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
r.	March 2, 2011	
	Group Health Education	$60.00
	Nutritional Medical Therapy	$400.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
	Measure Blood Oxygen Level	$35.00
s.	March 3, 2011	
	Votrient	$9,045.00
	Measure Blood Oxygen Level	$35.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
t.	March 4, 2011	
	Dressing change Hypafix	$120.00
	Lipid Panel	$50.00
	MG Magnesium	$50.00
	Dr. Valladares/Office/Outpatient Visit	$200.00
	Intravenous push, Singe Or	$125.00
	External Ambulatory infuse pus	$4,500.00
	Continue Flo Solution Kit	$268.00
	Measure Blood Oxygen Level	$35.00
	UA Urinalysis, Non-Auto W/	$25.00
	LD Lactate Dehydrogenase	$25.00
	Parenteral infuse. Pump portable	$100.00
	Avastin 10 mg	$7,424.02
	Chemo, IV infusion, 1 hr.	$198.00

u.	March 7, 2011	
	Monthly Case Management	$3,511.00
v.	March 21, 2011	
	Monthly Case Management	$3,511.00
x.	April 11, 2011	
	Monthly Case Management	$3,511.00
y.	April 28, 2011	
	Monthly Case Management	$3,511.00
z.	May 19, 2011	
	Monthly Case Management	$3,511.00
aa.	May 24, 2011	
	Monthly Case Management	$3,511.00
bb.	June 22, 2011	
	Monthly Case Management	$3,511.00
cc.	July 21, 2011	
	Monthly Case Management	$3,511.00
dd.	September 6, 2011	
	Monthly Case Management	$3,511.00

28. Many of the improper charges for evaluation, diagnosis and treatment of Patient A by the Burzynski Clinic were done at the direction and control of Respondent, and were for medically unnecessary services. Many of the improper charges for evaluation, diagnosis and treatment of Patient A by the Burzynski Clinic under the direction and control of Respondent were not adequately supported by documentation. These improper charges constituted violations of the Act and Board Rules.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); (4) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; (5) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper; and (6) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

29. Respondent inadequately supervised the activities of Burzynski Clinic employees acting under Respondent's supervision who were evaluating and treating Patient B. Respondent's inadequate supervision included failure to document his review of documents related to evaluation, diagnosis and treatment of Patient B.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

30. Respondent delegated professional medical responsibility or acts to employees of the Burzynski Clinic regarding the evaluation and treatment of Patient B when Respondent knew or had reason to know that those employees were not qualified by training, experience or licensure to perform the responsibility or acts. Those acts included the following:

a. Evaluation of Patient B's medical condition on or about February 7, 2011, February 8, 2011, February 9, 2011, February 10, 2011, February 11, 2011, February 12, 2011, February 14, 2011, February 15, 2011, February 16, 2011, February 17, 2011, February 18, 2011, February 21, 2011, February 22, 2011, February 23, 2011, February 24, 2011, February 25, 2011, February 28, 2011, March 1, 2011, March 2, 2011, March 3, 2011, March 4, 2011, March 21, 2011, May 24, 2011, June 16, 2011, June 17, 2011, July 1, 2011, July 5, 2011, July 6, 2011, July 7, 2011, August 19, 2011, and August 29, 2011.

b. Diagnosis of Patient B's medical condition on or about February 7, 2011, February 8, 2011, February 9, 2011, February 10, 2011, February 11, 2011, February 12, 2011, February 14, 2011, February 15, 2011, February 16, 2011, February 17, 2011, February 18, 2011, February 21, 2011, February 22, 2011, February 23, 2011, February 24, 2011, February 25, 2011, February 28, 2011, March 1, 2011, March 2, 2011, March 3, 2011, March 4, 2011, March 21, 2011, May 24, 2011, June 16, 2011, June 17, 2011, July 1, 2011, July 5, 2011, July 6, 2011, July 7, 2011, August 19, 2011, and August 29, 2011.

c. Making recommendations for treatment of Patient B's medical condition on or about February 7, 2011, February 8, 2011, February 9, 2011, February 10, 2011, February 11, 2011, February 12, 2011, February 14, 2011, February 15, 2011, February 16, 2011, February 17, 2011, February 18, 2011, February 21, 2011, February 22, 2011, February 23, 2011, February 24, 2011, February 25, 2011, February 28, 2011, March 1, 2011, March 2, 2011, March 3, 2011, March 4, 2011, March 21, 2011, May 24, 2011, June 16, 2011, June 17, 2011, July 1,

2011, July 5, 2011, July 6, 2011, July 7, 2011, August 19, 2011, and August 29, 2011.

d. Making decisions regarding the treatment of Patient B's medical condition on or about February 7, 2011, February 8, 2011, February 9, 2011, February 10, 2011, February 11, 2011, February 12, 2011, February 14, 2011, February 15, 2011, February 16, 2011, February 17, 2011, February 18, 2011, February 21, 2011, February 22, 2011, February 23, 2011, February 24, 2011, February 25, 2011, February 28, 2011, March 1, 2011, March 2, 2011, March 3, 2011, March 4, 2011, March 21, 2011, May 24, 2011, June 16, 2011, June 17, 2011, July 1, 2011, July 5, 2011, July 6, 2011, July 7, 2011, August 19, 2011, and August 29, 2011.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); and (3) Section 164.053(a)(9) of the Act, delegation of professional medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not qualified by training, experience or licensure to perform the responsibility or acts.

31. Respondent's recommendation and/or direction for the treatment of Patient B with various substances referenced above in Allegation No. B.22 violated the standard of care.

a. Review of prior history and records of prior treatment and related conditions.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by their failure to attempt to obtain and to review prior medical records for Patient B at the time that Respondent initially recommended and/or directed anti-cancer treatment for Patient B. These failures to obtain and review medical records of prior evaluation and treatment included:

a. Medical records of Patient B's evaluation and treatment in Ukraine prior to August 2010.

b. Medical records of Patient B's evaluation and treatment by Dr. Uwe Spetzger of Germany prior to February 7, 2011.

c. Medical records of Patient B's evaluation and treatment by Dr. Brandt after March 4, 2011.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document attempts to obtain and review prior medical records for Patient

B at the time that Respondent initially recommended and/or directed anti-cancer treatment for Patient B.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); and 190.8(1)(C); (4) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (5) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

b. Physical examination.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate physical examination of Patient B at the time that Respondent recommended and/or directed anti-cancer treatment for Patient B. These failures to perform an adequate physical examination included:

a. After the initial office visit physical examination in February 2011 during the time period of office visits in February 2011 and early March 2011.

b. During the nine month period between early March 2011 and when Respondent no longer made recommendations regarding Patient B's evaluation and treatment in September 2011.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standards of adequate documentation by failure to document performance of an adequate physical examination of Patient B at the time that Respondent recommended and/or directed anti-cancer treatment for Patient B.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; and (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed;

and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

c. Mental status examination.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate mental status examination at the time that Respondent recommended and/or directed anti-cancer treatment for Patient B. These failures to perform an adequate mental status examination included:

a. After the initial office visit physical examination in February 2011 during the time period of office visits in February 2011 and early March 2011.
b. During the nine month period between early March 2011 and when Respondent no longer made recommendations regarding Patient B's evaluation and treatment in September 2011.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate mental status examination at the time that Respondent recommended and/or directed anti-cancer treatment for Patient B. Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate mental status examination after initiating recommended anti-cancer treatments for Patient B. These failures to perform the elements of an adequate mental status examination included failure to determine:

a. the patient's ability to identify themselves;
b. the patient's awareness of their surroundings;
c. whether the patient is aware of what they are being seen for;
d. the patient's ability to make decisions for themselves;
e. the patient's ability to understand the directions for taking the medications;
f. the patient's awareness of the risks of the medications;
g. patient's frame of mind and general psychiatric condition, such as anxiety or depression, if any.

3) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to

adequately document a mental status examination at the time that Respondent recommended and/or directed anti-cancer treatment for Patient B.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); and 190.8(1)(C); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

d. Treatment plan.

1) The inadequate treatment plan documented by Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision for Patient B at the time that Respondent recommended and/or directed anti-cancer treatment for Patient B. Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision failed to include the following elements of a treatment plan that are required by the standard of care:

a. Objectives to measure treatment effectiveness, including a method for determining effectiveness of polypharmacy, when more than one substance is used to treat a patient during the same time period;
b. Objectives for alleviation of symptoms;
c. Monitoring of objectives of treatment effectiveness;
d. Monitoring of alleviation of symptoms;
e. Monitoring of side effects of treatment; and
f. Dosages and instructions for treatment medications.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document an adequate treatment plan at the time that Respondent recommended and/or directed anti-cancer treatment for Patient B.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); and 190.8(1)(C); (3)

Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

e. Over-all medical rationale.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to have an adequate medical rationale for evaluation, diagnosis and treatment at the time of Respondent recommendations and/or direction of anti-cancer therapy for Patient B.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document an adequate medical rationale for evaluation, diagnosis and treatment at the time of Respondent's recommendations and/or direction of anti-cancer therapy for Patient B.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); and 190.8(1)(C); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

f. Informed consent.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to adequately discuss about the risks and benefits of the treatment with Patient B at the time of Respondent recommendations and/or direction of anti-cancer therapy for Patient B.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standards of adequate documentation by failure to document an adequate discussion about the risks and benefits of the treatment with Patient B at the time of Respondent's recommendations and/or direction of anti-cancer therapy for Patient B.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (4) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (5) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

g. Discussion of treatment alternatives.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to adequately discuss alternative anti-cancer treatments with Patient B at the time of Respondent recommendations and/or direction of anti-cancer therapy for Patient B.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document alternative treatments discussed with Patient B at the time of Respondent's recommendations and/or direction of anti-cancer therapy for Patient B.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D), 190.8(1)(H); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

32. Respondent had an ownership interest in the pharmacy that dispensed phenylbutyrate and other drugs provided by the pharmacy owned by Respondent. Respondent's failure to disclose this ownership interest to Patient B violated the Act and Board Rules.

Violation

Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility.

33. Respondent billed multiple charges, as set forth in Section B.25, to Patient B for which there is not an adequate description of the service provided in the medical record. Respondent billed for services rendered by Dr. Robert Weaver, but Dr. Weaver did not provide any evaluation or care for Patient B. Respondent also, therefore, billed for these services and/or products improperly.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); (4) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; and (5) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper; and (6) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

34. Respondent directed the unnecessary measurement of Patient B's oxygen saturation. Patient B had no significant pulmonary disease, and the medial records are without justification for this testing. Respondent also, therefore, billed for these services and/or products improperly.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section

164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); (4) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; (5) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper; and (6) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

35. Respondent directed the unnecessary and costly laboratory testing for measures that are without demonstrable benefit to Patient B, including, at the initial visit, an echocardiogram, an assay of plasma VEGF, serum EGFR, and her-2. Respondent also, therefore, billed for these services and/or products improperly.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); (3) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; (4) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper.

36. Respondent had an ownership interest in the laboratory that performed the tests that Respondent directed. Respondent did not disclose this ownership interest to Patient B.

Violation

(1) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility.

37. Respondent failed to adequately inform Patient B of the risks and benefits of the therapies that Respondent recommended and/or directed for Patient B. Respondent's failure violated the Act and Board Rules.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section

164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

38. Respondent's recommendations and/or directions for the treatment of Patient B was non-therapeutic treatment.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

39. Respondent and other health care providers under Respondent's direction and control treated Patient B without regard to the potential combined toxicities of drugs used pursuant to Respondent's recommendations and directions. Respondent and other health care providers under Respondent's direction and control referenced the case reports of other physicians not associated with the Burzynski Clinic as support for combined use of the drugs recommended and administered to Patient B. In those referenced case reports of physicians not associated with the Burzynski Clinic, however, those drugs were only used individually or in other combinations besides the combinations of drugs used for Patient B by Respondent and other health care providers under Respondent's direction and control. In this regard, Respondent and other health care providers under Respondent's direction and control violated the standard of care for reasons including:

a. Patient B suffered considerable toxicity affects.

b. Respondent violated the standard of care by failing to have an adequate medical rationale for this simultaneous use of these agents in anti-cancer therapy.

c. Respondent violated standards of adequate documentation by failing to document an adequate medical rationale for this simultaneous use of these agents in anti-cancer therapy.

d. Respondent also failed to adequately inform Patient B of this increased risk.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

C. Specific Allegations: Violation of Standard of Care Patient C

1. In April 2010, Patient C received a diagnosis of mesothelioma. Imaging studies revealed submandibular metabolically active lymphadenopathy and mediastinal adenopathy.

2. Patient C declined a local physician's recommendation of chemotherapy and a surgical evaluation. His primary physicians recommended the anti-cancer medications cis-platin[18] and pemetrexed[19].

3. Patient C sought treatment at the Respondent's clinic and met with Respondent on or about May 14, 2010.

4. Prior to May 14, 2010, Patient C did not have a recent histological or pathological confirmation that he had any kind of cancer.

5. At the time that Patient C first presented to Respondent and other doctors at the Burzynski Clinic, Patient C was not in a medical condition requiring emergency or intensive medical care.

[18] Anti-cancer medication
[19] Anti-cancer medication

6. Patient C sought treatment by Respondent with antineoplastons in part due to reading or viewing statements referenced in Allegation No. G(5 and 6) herein below.

7. At the time of the initial meeting with Respondent, Patient C had not had a recent biopsy showing malignancy. Respondent did not order or recommend a biopsy before initiating treatment of Patient C. Respondent's order and/or recommendation of initiating anti-cancer treatment before obtaining a confirming biopsy or other relevant confirming test violated the standard of care.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D), 190.8(1)(G), and 190.8(1)(H); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

8. Respondent recommendation and/or direction to initiate anti-cancer treatment of Patient C without pathologic documentation of malignancy in Respondent's medical records for Patient C violated the standard of care and standards of adequate documentation.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D), 190.8(1)(G); 190.8(1)(H); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

9. Respondent was one of Patient C's treating physicians throughout Patient C's treatment directed by physicians working at the Burzynski Clinic. Patient C's treatment was initiated at the Burzynski Clinic pursuant to Respondent's recommendations and direction.

10. Respondent initiated treatment of Patient C without adequately documenting Respondent's medical rationale and discussion with Patient C about Respondent's pathologic diagnosis. Respondent initiated treatment of Patient C without adequately documenting Respondent's analysis of genomic screening and discussion with Patient C about Respondent's genotypic and phenotypic diagnosis.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; and (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C).

11. At the time the Patient C first met with Respondent and the other employees of the Burzynski Clinic, Respondent allowed Tolib Rakhmanov and Sheryll Acelar, persons who are not licensed physicians or health care providers in Texas or elsewhere in the United States of America, to represent to Patient C that Tolib Rakhmanov and Sheryll Acelar were licensed medical doctors practicing medicine in Texas. Respondent continued to allow Patient C and Patient C's wife to believe that Tolib Rakhmanov and Sheryll Acelar were licensed medical doctors practicing medicine in Texas throughout Patient C's treatment at the Burzynski Clinic.

12. Respondent and the other Burzynski Clinic employees under Respondent's supervision and control referred to Tolib Rakhmanov as "Dr. Rakhmanov" and Sheryll Acelar as "Dr. Acelar" in Patient C's and Patient C's wife's presence. Respondent reasonably knew that Tolib Rakhmanov and Sheryll Acelar signed documents, many of which were also signed by Patient C and Patient C's wife, in manners that identified themselves as medical doctors. Patient C and Patient C's wife reasonably believed that Tolib Rakhmanov and Sheryll Acelar were medical doctors licensed to practice medicine in the state of Texas. Respondent was responsible for the false, misleading and deceptive representation to Patient C and Patient C's wife that Tolib Rakhmanov and Sheryll Acelar were medical doctors licensed to practice medicine in the state of Texas.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct that is likely to deceive or defraud the public, as provided by Section 164.053, or injure the public. and (3) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

13. Tolib Rakhmanov and Sheryll Acelar, persons who are not licensed physicians or health care providers in Texas or elsewhere in the United States of America, performed medical tasks, that constituted the practice of medicine in the state of Texas in the evaluation, diagnosis and treatment of Patient C, including:

a. Evaluation of Patient C's medical condition on or about May 11, 2010, May 13, 2010, May 14, 2010, May 16, 2010, May 17, 2010, May 18, 2010, May 19, 2010, May 20, 2010, May 21, 2010, May 24, 2010, May 25, 2010, June 1, 2010, June 9, 2010, June 17, 2010, June 23, 2010, June 30, 2010, July 1, 2010, July 2, 2010, July 6, 2010, July 9, 2010, July 13, 2010, July 27, 2010, July 28, 2010, August 1, 2010, August 3, 2010, August 10, 2010, August 11, 2010, August 17, 2010, August 23, 2010, August 25, 2010, September 1, 2010, September 11, 2010, September 22, 2010, September 27, 2010, September 28, 2010, October 1, 2010, October 11, 2010, October 14, 2010, October 21, 2010, November 1, 2010, November 10, 2010, November 11, 2010, November 12, 2010, November 21, 2010, November 23, 2010, December 1, 2010, December 6, 2010, December 7, 2010, December 8, 2010, December 14, 2010, December 21, 2010, January 1, 2011, January 4, 2011, January 13, 2011, January 25, 2011, February 1, 2011, February 10, 2011, February 16, 2011, February 17, 2011, March 1, 2011, March 8, 2011, March 9, 2011, March 11, 2011, March 23, 2011, April 1, 2011, April 5, 2011, April 15, 2011, April 27, 2011, April 28, 2011, May 1, 2011, May 18, 2011, May 20, 2011, June 1, 2011, June 18, 2011, June 21, 2011, June 20, 2011, July 1, 2011, July 16, 2011, July 30, 2011, and August 31, 2011.

b. Diagnosis of Patient C's medical condition on or about May 11, 2010, May 13, 2010, May 14, 2010, May 16, 2010, May 17, 2010, May 18, 2010, May 19, 2010, May 20, 2010, May 21, 2010, May 24, 2010, May 25, 2010, June 1, 2010, June 9, 2010, June 17, 2010, June 23, 2010, June 30, 2010, July 1, 2010, July 2, 2010, July 6, 2010, July 9, 2010, July 13, 2010, July 27, 2010, July 28, 2010, August 1, 2010, August 3, 2010, August 10, 2010, August 11, 2010, August 17, 2010, August 23, 2010, August 25, 2010, September 1, 2010, September 11, 2010, September 22, 2010, September 27, 2010, September 28, 2010, October 1, 2010, October 11, 2010, October 14, 2010, October 21, 2010, November 1, 2010, November 10, 2010, November 11, 2010, November 12, 2010, November 21, 2010, November 23, 2010, December 1, 2010, December 6, 2010, December 7, 2010, December 8, 2010, December 14, 2010, December 21, 2010, January 1,

2011, January 4, 2011, January 13, 2011, January 25, 2011, February 1, 2011, February 10, 2011, February 16, 2011, February 17, 2011, March 1, 2011, March 8, 2011, March 9, 2011, March 11, 2011, March 23, 2011, April 1, 2011, April 5, 2011, April 15, 2011, April 27, 2011, April 28, 2011, May 1, 2011, May 18, 2011, May 20, 2011, June 1, 2011, June 18, 2011, June 21, 2011, June 20, 2011, July 1, 2011, July 16, 2011, July 30, 2011, and August 31, 2011.

c. Making recommendations for treatment of Patient C's medical condition on or about May 11, 2010, May 13, 2010, May 14, 2010, May 16, 2010, May 17, 2010, May 18, 2010, May 19, 2010, May 20, 2010, May 21, 2010, May 24, 2010, May 25, 2010, June 1, 2010, June 9, 2010, June 17, 2010, June 23, 2010, June 30, 2010, July 1, 2010, July 2, 2010, July 6, 2010, July 9, 2010, July 13, 2010, July 27, 2010, July 28, 2010, August 1, 2010, August 3, 2010, August 10, 2010, August 11, 2010, August 17, 2010, August 23, 2010, August 25, 2010, September 1, 2010, September 11, 2010, September 22, 2010, September 27, 2010, September 28, 2010, October 1, 2010, October 11, 2010, October 14, 2010, October 21, 2010, November 1, 2010, November 10, 2010, November 11, 2010, November 12, 2010, November 21, 2010, November 23, 2010, December 1, 2010, December 6, 2010, December 7, 2010, December 8, 2010, December 14, 2010, December 21, 2010, January 1, 2011, January 4, 2011, January 13, 2011, January 25, 2011, February 1, 2011, February 10, 2011, February 16, 2011, February 17, 2011, March 1, 2011, March 8, 2011, March 9, 2011, March 11, 2011, March 23, 2011, April 1, 2011, April 5, 2011, April 15, 2011, April 27, 2011, April 28, 2011, May 1, 2011, May 18, 2011, May 20, 2011, June 1, 2011, June 18, 2011, June 21, 2011, June 20, 2011, July 1, 2011, July 16, 2011, July 30, 2011, and August 31, 2011.

d. Making decisions regarding the treatment of Patient C's medical condition on or about May 11, 2010, May 13, 2010, May 14, 2010, May 16, 2010, May 17, 2010, May 18, 2010, May 19, 2010, May 20, 2010, May 21, 2010, May 24, 2010, May 25, 2010, June 1, 2010, June 9, 2010, June 17, 2010, June 23, 2010, June 30, 2010, July 1, 2010, July 2, 2010, July 6, 2010, July 9, 2010, July 13, 2010, July 27, 2010, July 28, 2010, August 1, 2010, August 3, 2010, August 10, 2010, August 11, 2010, August 17, 2010, August 23, 2010, August 25, 2010, September 1, 2010, September 11, 2010, September 22, 2010, September 27, 2010, September 28, 2010, October 1, 2010, October 11, 2010, October 14, 2010, October 21, 2010, November 1, 2010, November 10, 2010, November 11, 2010, November 12, 2010, November 21, 2010, November 23, 2010, December 1, 2010, December 6, 2010, December 7, 2010, December 8, 2010, December 14, 2010, December 21, 2010, January 1, 2011, January 4, 2011, January 13, 2011, January 25, 2011, February 1, 2011, February 10, 2011, February 16, 2011, February 17, 2011, March 1, 2011, March 8, 2011, March 9, 2011, March 11, 2011, March 23, 2011, April 1, 2011, April 5, 2011, April 15, 2011, April 27, 2011, April 28, 2011, May 1, 2011, May 18, 2011, May 20, 2011, June 1, 2011, June 18, 2011, June 21, 2011, June 20, 2011, July 1, 2011, July 16, 2011, July 30, 2011, and August 31, 2011.

14. Respondent directed and/or reasonably knew of and allowed Tolib Rakhmanov and Sheryll Acelar, persons who are not licensed physicians or health care providers in Texas or elsewhere in the United States of America, to perform medical tasks that constituted the practice of medicine in the state of Texas in the evaluation, diagnosis and treatment of Patient C. Respondent's direction, delegation and/or allowance of Tolib Rakhmanov's and Sheryll Acelar's performance of medical tasks that constituted the practice of medicine in the state of Texas in the evaluation, diagnosis and treatment of Patient C constituted inadequate supervision and delegating a person to perform medical tasks for which that person was not appropriately trained and/or licensed.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); (4) Section 164.053(a)(9) of the Act, delegation of professional medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not qualified by training, experience or licensure to perform the responsibility or acts.

15. After Respondent made recommendations for Patient C's treatment, Respondent continued to be Patient C's treating physician throughout Patient C's treatment by the Burzynski Clinic. Patient C was also treated by physicians who were working at the Burzynski Clinic and physicians were working in collaboration the Burzynski Clinic. All of these other physicians treated Patient C under Respondent's direction and control while Respondent was Patient C's treating physician.

16. Patient C's treatment was initiated at the Burzynski Clinic pursuant to Respondent's recommendations and direction.

17. Patient C had initially informed the Burzynski Clinic that Patient C wanted "antineoplaston" therapy rather than classic or other chemotherapy and surgical treatments. At

the time that Patient C presented to Respondent at the Burzynski Clinic on or about May 14, 2010, Patient C informed Respondent that Patient C wanted "antineoplaston" therapy rather than classic or other chemotherapy treatments.

18. Respondent failed to document his patient encounter with Patient C on or about May 14, 2010.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; and (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C).

19. Respondent informed Patient C that he would be treated initially with anti-cancer substances, but not antineoplastons. At the time Respondent made this representation, Respondent failed to inform Patient C that Respondent was not going to assist Patient C in obtaining access to being treated with antineoplastons. Therefore, Respondent's representation was false, misleading and deceptive.

Violation

Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct that is likely to deceive or defraud the public, as provided by Section 164.053, or injure the public.

20. Patient C had noticeable pleural effusion when he first presented to Respondent and the employees of the Burzynski Clinic under his supervision and control. Respondent and the employees of the Burzynski Clinic under his supervision and control failed to perform an adequate evaluation and differential diagnosis regarding this symptom. The failure of Respondent and the employees of the Burzynski Clinic under his supervision and control to perform an adequate evaluation and differential diagnosis regarding this symptom violated the standard of care and standards of adequate documentation. At the time of the initial meeting with Respondent, Respondent and the employees of the Burzynski Clinic under his supervision and control did not review pathology records of Patient C showing malignancy. Respondent and the employees of the Burzynski Clinic under his supervision and control did not review, order or recommend a biopsy before initiating treatment of Patient C. Respondent's order and/or

recommendation of initiating anti-cancer treatment before obtaining a confirming biopsy or other relevant confirming test violated the standard of care and standards of adequate documentation.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; and (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

21. After assuring Patient C that he would obtain the treatment he desired, Respondent and the employees of the Burzynski Clinic under his supervision and control directed Patient C to pay a large sum of money on retainer for the anti-cancer therapy by the Burzynski Clinic.

22. After assuring Patient C that he would obtain the treatment he desired, and after Patient C paid a large sum of money on retainer for anti-cancer therapy by the Burzynski Clinic, Respondent recommended and directed treatments for Patient C that did not include "antineoplaston" therapy. Respondent recommended and directed treatments with these other substances without adequately explaining to Patient C the difference in safety and efficacy between the therapy requested by Patient C and the therapy provided by Respondent and the employees of the Burzynski Clinic under his supervision and control.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C), 190.8(1)(H), and 190.8(1)(I); and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

23. Respondent recommended and directed that Patient C start treatment with beginning with phenylbutyrate, Avastin, Tarceva and Nexavar in May 2010. In November 2010,

imaging indicated that tumor growth was inhibited and spread minimal. In and after November 2010, Respondent recommended and directed that Patient C's medications be changed to Votrient, Afinitor, Zolinza, and Vectibix[20]. SW experienced disabling toxicities attributable to these drugs. Respondent did not recommend or direct a change from those medications until imaging in April 2011 showed disease progression. After reviewing the imaging from April 2011, Respondent only then recommended and directed that Patient C's medications be changed to carboplatin[21] and pemetrexed[22]. Respondent failed to have and failed to document an adequate medical rationale for a change of therapy when Patient C's symptoms related to cancer were improving in April 2011. Respondent also failed to adequately supervise employees to whom he delegated or to whom he attempted to delegate prescriptive authority regarding treatment of Patient C.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D); (4) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; (5) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician; and (6) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

24. Respondent recommended and directed that Patient C start various other substances for treatment including Nexavar, Tarceva, Avastin, Phenylbutyrate, and Dexamethasone[23].

26. Respondent's evaluation, diagnosis and treatment of Patient C ended at the end of January 2013.

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[20] Anti-cancer medication
[21] Anti-cancer medication
[22] Anti-cancer medication
[23] Anti-cancer medication

27. The Burzynski Clinic, under Respondent's direction and control, billed Patient B and Patient B's healthcare insurance carrier for services and charges that were medically unnecessary and not adequately supported by documentation including the following:

a.	May 11, 2010	
	Dr. Marquis/Office Consultation	$1,000.00
	Dr. Marquis/Prolonged Serv, W/O contact	$350.00
	VEG F Vascular Endothelial	$400.00
	EGFR Epidermal Growth Factor	$400.00
	Her-2/Neu	$350.00
	Molecular Mutation Identify	$200.00
	Genetic Examination	$40.00
b.	May 13, 2010	
	Tarceva 150 mg	$8,319.00
c.	May 14, 2010	
	Dr. Marquis/Office/Outpatient Visit	$125.00
	Sodium Phenylbutyrate 500 mg	$60.00
d.	May 15, 2010	
	Sodium Phenylbutyrate 500 mg	$120.00
e.	May 16, 2010	
	Sodium Phenylbutyrate 500 mg	$180.00
	Measure Blood Oxygen Level	$35.00
f.	May 17, 2010	
	Dr. Marquis/Office/Outpatient Visit	$125.00
	Lithium batteries, AA	$10.22
	Avastin 10 mg	$2,367.00
	Chemo, IV Infusion 1 hr.	$198.00
	Sodium Phenylbutyrate 500 mg	$240.00
g.	May 18, 2010	
	Sodium Phenylbutyrate 500 mg	$300.00
	Dr. Marquis/Office/Outpatient Visit	$125.00
	Dr. Marquis/Prolonged Serv in office	$350.00
h.	May 19, 2010	
	Dr. Marquis/Office/Outpatient Visit	$125.00
	Sodium Phenylbutyrate 500 mg	$720.00
	Nexavar 200 mg	$7,239.60
i.	May 20, 2010	
	Dr. Marquis/Office/Outpatient Visit	$200.00
	Add supplies – A10	$360.00
	Add supplies – A10	$72.00
	Add supplies – BL	$135.00
j.	May 21, 2010	

	Sodium Phenylbutyrate 500 mg	$1,440.00
k.	May 24, 2010	
	Phone E/M by Phys. 11-20 min	$100.00
	Sodium Phenylbutyrate 500 mg	$360.00
l.	May 25, 2010	
	Sodium Phenylbutyrate 500 mg	$2,520.00
m.	June 1, 2010	
	Sodium Phenylbutyrate 500 mg	$2,880.00
n.	June 9, 2010	
	Sodium Phenylbutyrate 500 mg	$2,880.00
o.	Jun 17, 2010	
	Sodium Phenylbutyrate 500 mg	$2,520.00
p.	June 23, 2010	
	Phone E/M by Phys 5-10 min	$125.00
q.	June 30, 2010	
	Add supplies – A10	$360.00
r.	July 1, 2010	
	Unidentified fee	$3,500.00
	Sodium Phenylbutyrate 500 mg	$2,880.00
s.	July 2, 2010	
	Phone E/M by Phys 5-10 min	$125.00
t.	July 6, 2010	
	Unidentified fee	$4,500.00
u.	July 9, 2010	
	Sodium Phenylbutyrate 500 mg	$3,600.00
v.	July 13, 2010	
	Phone E/M by Phys 5-10 min	$125.00
w.	July 19, 2010	
	Sodium Phenylbutyrate 500 mg	$2,520.00
x.	July 27, 2010	
	Phone E/M by Phys 5-10 min	$125.00
y.	July 28, 2010	
	VEG F Vascular Endothelial	$400.00
	EGFR Epidermal Growth Factor	$400.00
	Add supplies – A10	$360.00
z.	August 1, 2010	
	Sodium Phenylbutyrate 500 mg	$3,600.00
aa.	August 3, 2010	
	Unidentified fee	$4,500.00
bb.	August 10, 2010	
	Phone E/M by Phys 5-10 min	$125.00
cc.	August 11, 2010	
	Sodium Phenylbutyrate 500 mg	$2,520.00
dd.	August 10, 2010	

	Phone E/M by Phys 5-10 min	$125.00
ee.	August 17, 2010	
	Sodium Phenylbutyrate 500 mg	$2,520.00
ff.	August 23, 2010	
	Phone E/M by Phys 5-10 min	$125.00
gg.	August 25, 2010	
	Sodium Phenylbutyrate 500 mg	$2,520.00
hh.	September 1, 2010	
	Add Supplies – A10	$360.00
	Sodium Phenylbutyrate 500 mg	$3,600.00
	Unidentified fee	$4,500.00
ii.	September 11, 2010	
	Sodium Phenylbutyrate 500 mg	$3,600.00
jj.	September 22, 2010	
	Sodium Phenylbutyrate 500 mg	$2,520.00
kk.	September 27, 2010	
	Phone E/M by Phys 5-10 min	$125.00
ll.	September 28, 2010	
	Sodium Phenylbutyrate 500 mg	$1,080.00
mm.	October 1, 2010	
	Sodium Phenylbutyrate 500 mg	$3,600.00
nn.	October 11, 2010	
	Sodium Phenylbutyrate 500 mg	$3,600.00
oo.	October 14, 2010	
	Add Supplies – A10	$360.00
	Unidentified fee	$4,500.00
pp.	October 21, 2010	
	Sodium Phenylbutyrate 500 mg	$3,960.00
qq.	November 1, 2010	
	Sodium Phenylbutyrate 500 mg	$3,600.00
rr.	November 10, 2010	
	Add Supplies – A10	$324.00
	Add Supplies – A10	$180.00
xx.	November 11, 2010	
	Sodium Phenylbutyrate 500 mg	$3,600.00
	VEG F Vascular Endothelial	$400.00
	Her-2/Neu	$350.00
yy.	November 12, 2010	
	EGFR Epidermal Growth Factor	$400.00
zz.	November 21, 2010	
	Sodium Phenylbutyrate 500 mg	$1,440.00
aaa.	November 23, 2010	
	Phone E/M by Phys 5-10 min	$125.00
	Unidentified fee	$4,500.00

bbb.	November 21, 2010	
	Sodium Phenylbutyrate 500 mg	$1,080.00
ccc.	December 1, 2010	
	Sodium Phenylbutyrate 500 mg	$1,080.00
ddd.	December 6, 2010	
	Phone E/M by Phys 5-10 min	$125.00
eee.	December 7, 2010	
	Sodium Phenylbutyrate 500 mg	$2,160.00
fff.	December 8, 2010	
	Add Supplies – A10	$324.00
	Add Supplies – A10	$180.00
ggg.	December 14, 2010	
	Phone E/M by Phys 5-10 min	$125.00
hhh.	December 21, 2010	
	Phone E/M by Phys 5-10 min	$125.00
iii.	January 1, 2011	
	Sodium Phenylbutyrate 500 mg	$2,160.00
jjj.	January 4, 2011	
	Add Supplies – A10	$240.00
	Add Supplies – A10	$120.00
	Unidentified fee	$4,500.00
kkk.	January 13, 2011	
	Sodium Phenylbutyrate 500 mg	$2,160.00
lll.	January 25, 2011	
	Phone E/M by Phys 5-10 min	$125.00
mmm.	February 1, 2011	
	Sodium Phenylbutyrate 500 mg	$2,700.00
nnn.	February 16, 2011	
	Sodium Phenylbutyrate 500 mg	$2,340.00
ooo.	February 10, 2011	
	Add Supplies – A10	$240.00
	Add Supplies – A10	$120.00
	Unidentified fee	$4,500.00
ppp.	February 16, 2011	
	EGFR Epidermal Growth Factor	$400.00
qqq.	February 17, 2011	
	VEG F Vascular Endothelial	$400.00
	Her-2/Neu	$350.00
rrr.	March 1, 2011	
	Sodium Phenylbutyrate 500 mg	$1,440.00
sss.	March 8, 2011	
	Phone E/M by Phys 5-10 min	$125.00
ttt.	March 9, 2011	
	Add Supplies – A10	$240.00

	Add Supplies – A10	$120.00
uuu.	March 9, 2011	
	Sodium Phenylbutyrate 500 mg	$2,520.00
vvv.	March 11, 2011	
	Online E/M by Phys	$200.00
xxx.	March 23, 2011	
	Sodium Phenylbutyrate 500 mg	$1,620.00
yyy.	April 1, 2011	
	Sodium Phenylbutyrate 500 mg	$2,520.00
zzz.	April 5, 2011	
	Unidentified fee	$4,500.00
aaaa.	April 15, 2011	
	Sodium Phenylbutyrate 500 mg	$2,880.00
bbbb.	April 27, 2011	
	EGFR Epidermal Growth Factor	$400.00
cccc.	April 28, 2011	
	VEG F Vascular Endothelial	$400.00
	Her-2/Neu	$350.00
dddd.	May 1, 2011	
	Sodium Phenylbutyrate 500 mg	$2,700.00
eeee.	May 18, 2011	
	Add Supplies – A10	$240.00
	Add Supplies – A10	$120.00
	Unidentified fee	$4,500.00
ffff.	May 20, 2011	
	Sodium Phenylbutyrate 500 mg	$2,160.00
gggg.	June 1, 2011	
	Sodium Phenylbutyrate 500 mg	$3,600.00
hhhh.	June 18, 2011	
	Unidentified fee	$15,665.61
iiii.	June 21, 2011	
	Sodium Phenylbutyrate 500 mg	$1,800.00
jjjj.	June 20, 2011	
	Unidentified fee	$4,500.00
kkkk.	July 1, 2011	
	Sodium Phenylbutyrate 500 mg	$2,700.00
llll.	July 16, 2011	
	Sodium Phenylbutyrate 500 mg	$2,160.00
mmmm.	July 30, 2011	
	Sodium Phenylbutyrate 500 mg	$24.00
nnnn.	August 31, 2011	
	Monthly Case Management	$4,500.00

28. Many of the improper charges for evaluation, diagnosis and treatment of Patient A by the Burzynski Clinic were done at the direction and control of Respondent, and were for medically unnecessary services. Many of the improper charges for evaluation, diagnosis and treatment of Patient A by the Burzynski Clinic under the direction and control of Respondent were not adequately supported by documentation. These improper charges constituted violations of the Act and Board Rules.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); (3) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; (4) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper; and (5) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

29. Respondent inadequately supervised the activities of Burzynski Clinic employees acting under Respondent's supervision who were evaluating and treating Patient C. Respondent's inadequate supervision included failure to document his review of documents related to evaluation, diagnosis and treatment of Patient C.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

30. Respondent delegated professional medical responsibility or acts to employees of the Burzynski Clinic regarding the evaluation and treatment of Patient C when Respondent knew

or had reason to know that those employees were not qualified by training, experience or licensure to perform the responsibility or acts. These acts included the following:

a. Evaluation of Patient C's medical condition on or about May 11, 2010, May 13, 2010, May 14, 2010, May 16, 2010, May 17, 2010, May 18, 2010, May 19, 2010, May 20, 2010, May 21, 2010, May 24, 2010, May 25, 2010, June 1, 2010, June 9, 2010, June 17, 2010, June 23, 2010, June 30, 2010, July 1, 2010, July 2, 2010, July 6, 2010, July 9, 2010, July 13, 2010, July 27, 2010, July 28, 2010, August 1, 2010, August 3, 2010, August 10, 2010, August 11, 2010, August 17, 2010, August 23, 2010, August 25, 2010, September 1, 2010, September 11, 2010, September 22, 2010, September 27, 2010, September 28, 2010, October 1, 2010, October 11, 2010, October 14, 2010, October 21, 2010, November 1, 2010, November 10, 2010, November 11, 2010, November 12, 2010, November 21, 2010, November 23, 2010, December 1, 2010, December 6, 2010, December 7, 2010, December 8, 2010, December 14, 2010, December 21, 2010, January 1, 2011, January 4, 2011, January 13, 2011, January 25, 2011, February 1, 2011, February 10, 2011, February 16, 2011, February 17, 2011, March 1, 2011, March 8, 2011, March 9, 2011, March 11, 2011, March 23, 2011, April 1, 2011, April 5, 2011, April 15, 2011, April 27, 2011, April 28, 2011, May 1, 2011, May 18, 2011, May 20, 2011, June 1, 2011, June 18, 2011, June 21, 2011, June 20, 2011, July 1, 2011, July 16, 2011, July 30, 2011, and August 31, 2011.

b. Diagnosis of Patient C's medical condition on or about May 11, 2010, May 13, 2010, May 14, 2010, May 16, 2010, May 17, 2010, May 18, 2010, May 19, 2010, May 20, 2010, May 21, 2010, May 24, 2010, May 25, 2010, June 1, 2010, June 9, 2010, June 17, 2010, June 23, 2010, June 30, 2010, July 1, 2010, July 2, 2010, July 6, 2010, July 9, 2010, July 13, 2010, July 27, 2010, July 28, 2010, August 1, 2010, August 3, 2010, August 10, 2010, August 11, 2010, August 17, 2010, August 23, 2010, August 25, 2010, September 1, 2010, September 11, 2010, September 22, 2010, September 27, 2010, September 28, 2010, October 1, 2010, October 11, 2010, October 14, 2010, October 21, 2010, November 1, 2010, November 10, 2010, November 11, 2010, November 12, 2010, November 21, 2010, November 23, 2010, December 1, 2010, December 6, 2010, December 7, 2010, December 8, 2010, December 14, 2010, December 21, 2010, January 1, 2011, January 4, 2011, January 13, 2011, January 25, 2011, February 1, 2011, February 10, 2011, February 16, 2011, February 17, 2011, March 1, 2011, March 8, 2011, March 9, 2011, March 11, 2011, March 23, 2011, April 1, 2011, April 5, 2011, April 15, 2011, April 27, 2011, April 28, 2011, May 1, 2011, May 18, 2011, May 20, 2011, June 1, 2011, June 18, 2011, June 21, 2011, June 20, 2011, July 1, 2011, July 16, 2011, July 30, 2011, and August 31, 2011.

c. Making recommendations for treatment of Patient C's medical condition on or about May 11, 2010, May 13, 2010, May 14, 2010, May 16, 2010, May 17, 2010, May 18, 2010, May 19, 2010, May 20, 2010, May 21, 2010, May 24, 2010, May 25, 2010, June 1, 2010, June 9, 2010, June 17, 2010, June 23, 2010, June 30, 2010, July 1, 2010, July 2, 2010, July 6, 2010, July 9, 2010, July 13, 2010, July

27, 2010, July 28, 2010, August 1, 2010, August 3, 2010, August 10, 2010, August 11, 2010, August 17, 2010, August 23, 2010, August 25, 2010, September 1, 2010, September 11, 2010, September 22, 2010, September 27, 2010, September 28, 2010, October 1, 2010, October 11, 2010, October 14, 2010, October 21, 2010, November 1, 2010, November 10, 2010, November 11, 2010, November 12, 2010, November 21, 2010, November 23, 2010, December 1, 2010, December 6, 2010, December 7, 2010, December 8, 2010, December 14, 2010, December 21, 2010, January 1, 2011, January 4, 2011, January 13, 2011, January 25, 2011, February 1, 2011, February 10, 2011, February 16, 2011, February 17, 2011, March 1, 2011, March 8, 2011, March 9, 2011, March 11, 2011, March 23, 2011, April 1, 2011, April 5, 2011, April 15, 2011, April 27, 2011, April 28, 2011, May 1, 2011, May 18, 2011, May 20, 2011, June 1, 2011, June 18, 2011, June 21, 2011, June 20, 2011, July 1, 2011, July 16, 2011, July 30, 2011, and August 31, 2011.

d. Making decisions regarding the treatment of Patient C's medical condition on or about May 11, 2010, May 13, 2010, May 14, 2010, May 16, 2010, May 17, 2010, May 18, 2010, May 19, 2010, May 20, 2010, May 21, 2010, May 24, 2010, May 25, 2010, June 1, 2010, June 9, 2010, June 17, 2010, June 23, 2010, June 30, 2010, July 1, 2010, July 2, 2010, July 6, 2010, July 9, 2010, July 13, 2010, July 27, 2010, July 28, 2010, August 1, 2010, August 3, 2010, August 10, 2010, August 11, 2010, August 17, 2010, August 23, 2010, August 25, 2010, September 1, 2010, September 11, 2010, September 22, 2010, September 27, 2010, September 28, 2010, October 1, 2010, October 11, 2010, October 14, 2010, October 21, 2010, November 1, 2010, November 10, 2010, November 11, 2010, November 12, 2010, November 21, 2010, November 23, 2010, December 1, 2010, December 6, 2010, December 7, 2010, December 8, 2010, December 14, 2010, December 21, 2010, January 1, 2011, January 4, 2011, January 13, 2011, January 25, 2011, February 1, 2011, February 10, 2011, February 16, 2011, February 17, 2011, March 1, 2011, March 8, 2011, March 9, 2011, March 11, 2011, March 23, 2011, April 1, 2011, April 5, 2011, April 15, 2011, April 27, 2011, April 28, 2011, May 1, 2011, May 18, 2011, May 20, 2011, June 1, 2011, June 18, 2011, June 21, 2011, June 20, 2011, July 1, 2011, July 16, 2011, July 30, 2011, and August 31, 2011.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); and (4) Section 164.053(a)(9) of the Act, delegation of professional medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not qualified by training, experience or licensure to perform the responsibility or acts.

31. Respondent's recommendation and/or direction for the treatment of Patient C with various substances referenced above in Allegations No. C.24 and C.25 violated the standard of care.

a. Physical examination.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate physical examination of Patient C at the time that Respondent recommended and/or directed anti-cancer treatment for Patient C. These failures to perform an adequate physical examination included:

a. After the initial office visit physical examination in May 2010 during the time period of office visits in May 2010.
b. During the 12-month time period between May 2010 and the end of August 2011.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standards of adequate documentation by failure to document performance of an adequate physical examination of Patient C at the time that Respondent recommended and/or directed anti-cancer treatment for Patient C.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; and (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

b. Mental status examination.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate mental status examination at the time that Respondent recommended and/or directed anti-cancer treatment for Patient C. These failures to perform an adequate mental status examination included:

a. After the initial office visit physical examination in May 2010 during the time period of office visits in May 2010.
b. During the 12-month time period between May 2010 and the end of August 2011.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate mental status examination at the time that Respondent recommended and/or directed anti-cancer treatment for Patient C. Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate mental status examination after initiating recommended anti-cancer treatments for Patient C. These failures to perform the elements of an adequate mental status examination included failure to determine:

a. the patient's ability to identify themselves;
b. the patient's awareness of their surroundings;
c. whether the patient is aware of what they are being seen for;
d. the patient's ability to make decisions for themselves;
e. the patient's ability to understand the directions for taking the medications;
f. the patient's awareness of the risks of the medications;
g. patient's frame of mind and general psychiatric condition, such as anxiety or depression, if any.

3) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document a mental status examination at the time that Respondent recommended and/or directed anti-cancer treatment for Patient C.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); and 190.8(1)(C); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

c. Treatment plan.

1) The inadequate treatment plan documented by Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision for Patient C at the time that Respondent recommended and/or directed anti-cancer treatment for Patient C. Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision failed to include the following elements of a treatment plan that are required by the standard of care:

a. Objectives to measure treatment effectiveness, including a method for determining effectiveness of polypharmacy, when more than one substance is used to treat a patient during the same time period;
b. Objectives for alleviation of symptoms;
c. Monitoring of objectives of treatment effectiveness;
d. Monitoring of alleviation of symptoms;
e. Monitoring of side effects of treatment; and
f. Dosages and instructions for treatment medications.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document an adequate treatment plan at the time that Respondent recommended and/or directed anti-cancer treatment for Patient C.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); and 190.8(1)(C); (4) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (5) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

d. Over-all medical rationale.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to have an adequate medical

rationale for evaluation, diagnosis and treatment at the time of Respondent recommendations and/or direction of anti-cancer therapy for Patient C.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document an adequate medical rationale for evaluation, diagnosis and treatment at the time of Respondent's recommendations and/or direction of anti-cancer therapy for Patient C.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); and 190.8(1)(C); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

e. Informed consent.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to adequately discuss about the risks and benefits of the treatment with Patient C at the time of Respondent recommendations and/or direction of anti-cancer therapy for Patient C.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standards of adequate documentation by failure to document an adequate discussion about the risks and benefits of the treatment with Patient C at the time of Respondent's recommendations and/or direction of anti-cancer therapy for Patient C.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (3) Section 164.053(a)(5) of the Act,

prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

f. Discussion of treatment alternatives.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to adequately discuss alternative anti-cancer treatments with Patient C at the time of Respondent recommendations and/or direction of anti-cancer therapy for Patient C.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document alternative treatments discussed with Patient C at the time of Respondent's recommendations and/or direction of anti-cancer therapy for Patient C.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D), 190.8(1)(H); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

32. Respondent had an ownership interest in the pharmacy that dispensed phenylbutyrate and other drugs provided by the pharmacy owned by Respondent. Respondent's failure to disclose this ownership interest to Patient C violated the Act and Board Rules.

Violation

(1) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility.

33. Respondent billed multiple charges, as set forth in Section C.27 above, to Patient C for which there is no adequate description of the service or product in the medical record. Respondent also, therefore, billed for these services and/or products improperly.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); (3) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; (4) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper; and (5) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

34. Respondent directed the unnecessary measurement of Patient C's oxygen saturation. Patient C had no significant pulmonary disease, and the medial records are without justification for this testing. Respondent also, therefore, billed for these services and/or products improperly.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); (3) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; (4) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper.

35. Respondent directed the unnecessary and costly laboratory testing for measures that are without demonstrable benefit to Patient C, including, at the initial visit, an echocardiogram, an assay of plasma VEGF, serum EGFR, and her-2. Respondent also, therefore, billed for these services and/or products improperly.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); (3) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; (4) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper.

36. Respondent had an ownership interest in the laboratory that performed the tests that Respondent directed. Respondent did not disclose this ownership interest to Patient C.

Violation

(1) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility.

37. Respondent failed to adequately inform Patient C of the risks and benefits of the therapies that Respondent recommended and/or directed for Patient C. Respondent's failure violated the Act and Board Rules.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

38. Respondent's recommendations and/or directions for the treatment of Patient C was non-therapeutic treatment.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed;

and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

39. Respondent and other health care providers under Respondent's direction and control treated Patient C without regard to the potential combined toxicities of drugs used pursuant to Respondent's recommendations and directions. Respondent and other health care providers under Respondent's direction and control referenced the case reports of other physicians not associated with the Burzynski Clinic as support for combined use of the drugs recommended and administered to Patient C. In those referenced case reports of physicians not associated with the Burzynski Clinic, however, those drugs were only used individually or in other combinations besides the combinations of drugs used for Patient C by Respondent and other health care providers under Respondent's direction and control. In this regard, Respondent and other health care providers under Respondent's direction and control violated the standard of care for reasons including:

a. Patient C suffered considerable toxicity affects.
b. Respondent violated the standard of care by failing to have an adequate medical rationale for this simultaneous use of these agents in anti-cancer therapy.
c. Respondent violated standards of adequate documentation by failing to document an adequate medical rationale for this simultaneous use of these agents in anti-cancer therapy.
d. Respondent also failed to adequately inform Patient C of this increased risk.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

D. Specific Allegations: Violation of Standard of Care Patient D

1. In May 2010, Patient D received a diagnosis of brain tumor. A surgical removal of the tumor mass was performed on May 10, 2010. In November 2010, Patient D received

imaging studies that revealed new lesions of the brain and spine. Patient D received radiation therapy and chemotherapy from an oncologist.

2. After Patient D experienced side effects from the chemotherapy medications, Patient D declined the oncologist's advice to continue chemotherapy at lower doses.

3. Patient D sought treatment at the Respondent's clinic and met with Respondent on or about June 7, 2011.

4. Between the time that Patient D had the brain tumor surgery in May 2010 and June 7, 2011, Patient D did not have a histological or pathological confirmation that he still had any kind of cancer. Respondent's failure to obtain a histological or pathological confirmation of cancer prior to initiating treatment was a violation of the standard of care.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D), 190.8(1)(G), and 190.8(1)(H); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

5. At the time that Patient D first presented to Respondent and other doctors at the Burzynski Clinic, Patient D was not in a medical condition requiring emergency or intensive medical care.

6. At the time of the initial meeting with Respondent, Patient D had not had a biopsy showing malignancy. Respondent did not order or recommend a biopsy before initiating treatment of Patient D. Respondent's order and/or recommendation of initiating anti-cancer treatment before obtaining a confirming biopsy or other relevant confirming test violated the standard of care.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D), 190.8(1)(G), and 190.8(1)(H); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

7. Respondent initiated treatment of Patient D without adequately documenting Respondent's medical rationale and discussion with Patient D about Respondent's pathologic diagnosis. Respondent initiated treatment of Patient D without adequately documenting Respondent's analysis of genomic screening and discussion with Patient D about Respondent's genotypic and phenotypic diagnosis.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; and (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C).

8. Respondent recommendation and/or direction to initiate anti-cancer treatment of Patient D without pathologic documentation of malignancy in Respondent's medical records for Patient D violated the standard of care and standards of adequate documentation.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D), 190.8(1)(G); 190.8(1)(H); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

9. Patient D sought treatment by Respondent with antineoplastons in part due to reading or viewing statements referenced in Allegation No. G(5 and 6) herein below.

10. Respondent was one of Patient D's treating physicians throughout Patient D's treatment directed by physicians working at the Burzynski Clinic. Patient D's treatment was initiated at the Burzynski Clinic pursuant to Respondent's recommendations and direction.

11. At the time the Patient D first met with Respondent and the other employees of the Burzynski Clinic, Respondent allowed Sheryll Acelar, a person who is not a licensed physician or health care provider in Texas or elsewhere in the United States of America, to represent to Patient D that Sheryll Acelar was a licensed medical doctor practicing medicine in Texas. Respondent continued to allow Patient D and Patient D's wife to believe that Sheryll Acelar was a licensed medical doctor practicing medicine in Texas throughout Patient D's treatment at the Burzynski Clinic.

12. Respondent and the other Burzynski Clinic employees under Respondent's supervision and control referred to Sheryll Acelar as "Dr. Acelar" in Patient D's and Patient D's wife's presence. Respondent reasonably knew that Sheryll Acelar signed documents, many of which were also signed by Patient D and Patient D's wife, in manners that identified himself as a medical doctor. Patient D and Patient D's wife reasonably believed that Sheryll Acelar was a medical doctor licensed to practice medicine in the state of Texas. Respondent was responsible for the false, misleading and deceptive representation to Patient D and Patient D's wife that Sheryll Acelar was a medical doctor licensed to practice medicine in the state of Texas.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct that is likely to deceive or defraud the public, as provided by Section 164.053, or injure the public.

13. Sheryll Acelar, a person who is not a licensed physician or health care provider in Texas or elsewhere in the United States of America, performed medical tasks that constituted the practice of medicine in the state of Texas in the evaluation, diagnosis and treatment of Patient D.

a. Evaluation of Patient D's medical condition on or about June 7, 2011, June 10, 2011, June 13, 2011, and July 1, 2011.

b. Diagnosis of Patient D's medical condition on or about June 7, 2011, June 10, 2011, June 13, 2011, and July 1, 2011.

c. Making recommendations for treatment of Patient D's medical condition on or about June 7, 2011, June 10, 2011, June 13, 2011, and July 1, 2011.

d. Making decisions regarding the treatment of Patient D's medical condition on or about June 7, 2011, June 10, 2011, June 13, 2011, and July 1, 2011.

14. Respondent directed and/or reasonably knew of and allowed Sheryll Acelar, a person who is not a licensed physician or health care provider in Texas or elsewhere in the United States of America, to perform medical tasks that constituted the practice of medicine in the state of Texas in the evaluation, diagnosis and treatment of Patient D. Respondent's direction, delegation and/or allowance of Sheryll Acelar's performance of medical tasks that constituted the practice of medicine in the state of Texas in the evaluation, diagnosis and treatment of Patient D constituted inadequate supervision and delegating a person to perform medical tasks for which that person was not appropriately trained and/or licensed.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician; and (5) Section 164.053(a)(9) of the Act, delegation of professional medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not qualified by training, experience or licensure to perform the responsibility or acts.

15. After Respondent made recommendations for Patient D's treatment, Respondent continued to be Patient D's treating physician throughout Patient D's treatment by the Burzynski Clinic. Patient D was also treated by physicians who were working at the Burzynski Clinic and physicians were working in collaboration the Burzynski Clinic. All of these other physicians treated Patient D under Respondent's direction and control while Respondent was Patient D's treating physician.

16. Patient D had initially informed the Burzynski Clinic that Patient D wanted "antineoplaston" therapy rather than classic or other chemotherapy treatments. At the time that Patient D presented to Respondent at the Burzynski Clinic on or about June 7, 2011, Patient D informed Respondent that Patient D wanted "antineoplaston" therapy rather than classic or other chemotherapy treatments.

17. Respondent informed Patient D that he would be considered for antineoplaston therapy. At the time Respondent made this representation, Respondent failed to inform Patient D that he did not meet the criteria for inclusion in a clinical study of antineoplaston therapy. Therefore, Respondent's representation was false, misleading and deceptive.

Violation

Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct that is likely to deceive or defraud the public, as provided by Section 164.053, or injure the public.

18. After assuring Patient D that he would obtain the treatment he desired, Respondent and the employees of the Burzynski Clinic under his supervision and control directed Patient D to pay a large sum of money on retainer for the anti-cancer therapy by the Burzynski Clinic.

19. After assuring Patient D that he would obtain the treatment he desired, and after Patient D paid a large sum of money on retainer for anti-cancer therapy by the Burzynski Clinic, Respondent recommended and directed treatments for Patient D that did not include "antineoplaston" therapy.

20. Respondent's recommendations included the medications that Patient D's previous oncologist had recommended that Patient D continue. Respondent recommended and directed treatments with these other substances without adequately explaining to Patient D the difference in safety and efficacy between the therapy requested by Patient D and the therapy provided by Respondent and the employees of the Burzynski Clinic under his supervision and control.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C), 190.8(1)(H), and 190.8(1)(I); and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

21. Respondent recommended and directed that Patient D start treatment with phenylbutyrate, Temodar[24], Avastin, Tarceva, Afinitor, and Votrient.

22. Patient D decided to not initiate Respondent's recommendation and to not continue to obtain medical care from Respondent.

23. Respondent's evaluation, diagnosis and treatment of Patient D ended in July 2011.

24. The Burzynski Clinic, under Respondent's direction and control, billed Patient D and Patient B's healthcare insurance carrier for services and charges that were medically unnecessary and not adequately supported by documentation including the following:

a. June 7, 2011

EGFR Epidermal Growth Factor	$400.00
Dr. Marquis/Office Consultation	$1,000.00
Molecule Isolate Nucleic	$142.00
Dr. Marquis/Prolonged Ser. W/O Contact	$150.00
Her-2/Neu	$350.00
Molecular diagnostics	$40.00
VEG F Vascular Endothelial	$400.00
Molecular Mutation Identify	$200.00
Dr. Marquis/Prolonged Ser. W/O Contact	$350.00
Genetic Examination	$40.00
Electrolyte Panel	$25.00

b. June 8, 2011 through July 1, 2011

All services which were not itemized in billing sent to Patient D

[24] Anti-cancer medication

(Billing for these dates is missing from Patient D's billing records)

25. Many of the improper charges for evaluation, diagnosis and treatment of Patient A by the Burzynski Clinic were done at the direction and control of Respondent, and were for medically unnecessary services. Many of the improper charges for evaluation, diagnosis and treatment of Patient A by the Burzynski Clinic under the direction and control of Respondent were not adequately supported by documentation. These improper charges constituted violations of the Act and Board Rules.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); (4) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; (5) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper; and (6) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

26. Respondent inadequately supervised the activities of Burzynski Clinic employees acting under Respondent's supervision who were evaluating and treating Patient D. Respondent's inadequate supervision included failure to document his review of documents related to evaluation, diagnosis and treatment of Patient D.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

27. Respondent delegated professional medical responsibility or acts to employees of the Burzynski Clinic regarding the evaluation and treatment of Patient D when Respondent knew or had reason to know that those employees were not qualified by training, experience or licensure to perform the responsibility or acts. These employees included Alejandro Marquis, M.D. and Sheryll Acelar. Those acts included the following:

a. Evaluation of Patient D's medical condition on or about June 7, 2011, June 10, 2011, June 13, 2011, and July 1, 2011.
b. Diagnosis of Patient D's medical condition on or about June 7, 2011, June 10, 2011, June 13, 2011, and July 1, 2011.
c. Making recommendations for treatment of Patient D's medical condition on or about June 7, 2011, June 10, 2011, June 13, 2011, and July 1, 2011.
d. Making decisions regarding the treatment of Patient D's medical condition on or about June 7, 2011, June 10, 2011, June 13, 2011, and July 1, 2011.

Violation

(1) Section 157.001 of the Act, responsibility of a physician for medical acts delegated to persons acting under the physician's supervision; (2) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (3) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician; and (5) Section 164.053(a)(9) of the Act, delegation of professional medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not qualified by training, experience or licensure to perform the responsibility or acts.

28. Respondent's recommendation and/or direction for the treatment of Patient D with various substances referenced above in Allegation D.21 violated the standard of care.

a. Physical examination.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate physical examination of Patient D at the time that Respondent recommended and/or directed anti-cancer treatment for Patient D. These failures to perform an adequate physical examination included:

a. At the time of the initial office visit physical examination on or about June 7, 2011.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standards of adequate documentation by failure to document performance of an adequate physical examination of Patient D at the time that Respondent recommended and/or directed anti-cancer treatment for Patient D.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; and (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

b. Mental status examination.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate mental status examination at the time that Respondent recommended and/or directed anti-cancer treatment for Patient D. These failures to perform an adequate mental status examination included:

a. At the time of the initial office visit physical examination on or about June 7, 2011.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate mental status examination at the time that Respondent recommended and/or directed anti-cancer treatment for Patient D. Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate mental status examination after initiating recommended anti-cancer treatments for Patient D. These failures to perform the elements of an adequate mental status examination included failure to determine:

a. the patient's ability to identify themselves;
b. the patient's awareness of their surroundings;
c. whether the patient is aware of what they are being seen for;

d. the patient's ability to make decisions for themselves;
e. the patient's ability to understand the directions for taking the medications;
f. the patient's awareness of the risks of the medications;
g. patient's frame of mind and general psychiatric condition, such as anxiety or depression, if any.

3) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document a mental status examination at the time that Respondent recommended and/or directed anti-cancer treatment for Patient D.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); and 190.8(1)(C); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

c. Treatment plan.

1) The inadequate treatment plan documented by Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision for Patient D at the time that Respondent recommended and/or directed anti-cancer treatment for Patient D. Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision failed to include the following elements of a treatment plan that are required by the standard of care:

a. Objectives to measure treatment effectiveness, including a method for determining effectiveness of polypharmacy, when more than one substance is used to treat a patient during the same time period;
b. Objectives for alleviation of symptoms;
c. Monitoring of objectives of treatment effectiveness;
d. Monitoring of alleviation of symptoms;
e. Monitoring of side effects of treatment; and
f. Dosages and instructions for treatment medications.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document an adequate treatment plan at the time that Respondent recommended and/or directed anti-cancer treatment for Patient D.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); and 190.8(1)(C); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

d. Over-all medical rationale.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to have an adequate medical rationale for evaluation, diagnosis and treatment at the time of Respondent recommendations and/or direction of anti-cancer therapy for Patient D.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document an adequate medical rationale for evaluation, diagnosis and treatment at the time of Respondent's recommendations and/or direction of anti-cancer therapy for Patient D.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); and 190.8(1)(C); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

e. Informed consent.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to adequately discuss about the risks and benefits of the treatment with Patient D at the time of Respondent recommendations and/or direction of anti-cancer therapy for Patient D.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standards of adequate documentation by failure to document an adequate discussion about the risks and benefits of the treatment with Patient D at the time of Respondent's recommendations and/or direction of anti-cancer therapy for Patient D.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

f. Discussion of treatment alternatives.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to adequately discuss alternative anti-cancer treatments with Patient D at the time of Respondent recommendations and/or direction of anti-cancer therapy for Patient D.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document alternative treatments discussed with Patient D at the time of Respondent's recommendations and/or direction of anti-cancer therapy for Patient D.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D), 190.8(1)(H); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

29. Respondent had an ownership interest in the pharmacy that dispensed phenylbutyrate and other drugs provided by the pharmacy owned by Respondent. Respondent's failure to disclose this ownership interest to Patient D violated the Act and Board Rules.

Violation

Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility.

30. Respondent billed multiple charges, as set forth in Section D.24 above, to Patient D for which there is no adequate description of the service or product in the medical record. Respondent also, therefore, billed for these services and/or products improperly.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); (3) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; (4) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper; and (5) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

31. Respondent recommended and directed the simultaneous use of phenylbutyrate, Afinitor and Tarceva for Patient D. There are other overlapping side effects of these three medications that can result in renal failure when taken at the same time. Respondent failed to have and to document an adequate medical rationale that justified the simultaneous use of these

medications. Respondent's recommendation and direction of simultaneous use of these medications was a violation of the standard of care.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); (3) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; (4) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper.

33. Respondent directed the unnecessary and costly laboratory testing for measures that are without demonstrable benefit to Patient D, including, at the initial visit, an echocardiogram, an assay of plasma VEGF, serum EGFR, and her-2. Respondent also, therefore, billed for these services and/or products improperly.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); (3) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; (4) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper.

34. Respondent had an ownership interest in the laboratory that performed the tests that Respondent directed. Respondent did not disclose this ownership interest to Patient D.

Violation

(1) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility.

35. Respondent failed to adequately inform Patient D of the risks and benefits of the therapies that Respondent recommended and/or directed for Patient D. Respondent's failure violated the Act and Board Rules.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

36. Respondent's recommendations and/or directions for the treatment of Patient D was non-therapeutic treatment.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

37. Respondent and other health care providers under Respondent's direction and control treated Patient D without regard to the potential combined toxicities of drugs recommended pursuant to Respondent's recommendations and directions. Respondent and other health care providers under Respondent's direction and control referenced the case reports of other physicians not associated with the Burzynski Clinic as support for combined use of the drugs recommended and administered to Patient D. In those referenced case reports of physicians not associated with the Burzynski Clinic, however, those drugs were only used individually or in other combinations besides the combinations of drugs recommended for use for Patient D by Respondent and other health care providers under Respondent's direction and control. In this regard, Respondent and other health care providers under Respondent's direction and control violated the standard of care for reasons including:

a. Such recommendations put Patient C at risk for considerable toxicity affects.

b. Respondent violated the standard of care by failing to have an adequate medical rationale for this simultaneous use of these agents in anti-cancer therapy.

c. Respondent violated standards of adequate documentation by failing to document an adequate medical rationale for this simultaneous use of these agents in anti-cancer therapy.

d. Respondent also failed to adequately inform Patient C of this increased risk.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

E. Specific Allegations: Violation of Standard of Care Patient E

1. In December 2010, after suffering acute renal failure, Patient E received a biopsy-based diagnosis of malignant chromophobe renal cell carcinoma. This is a relatively rare cancer.[25] Imaging studies in July 2011 revealed residual metastatic disease centered within the left T3 transverse process of the kidney.

2. Because he had previously suffered significant side effects from chemotherapy, including Votrient, Patient E declined a local physician's recommendation of additional chemotherapy.

3. Patient E sought treatment at the Respondent's clinic and met with Respondent on or about September 7, 2011.

4. Between December 2010 and September 7, 2011, Patient E did not have a more recent histological or pathological confirmation that he had any kind of cancer.

[25]Malignant chromophobe renal cell carcinoma is a rare condition according to the National Institute of Health. See http://cancergenome.nih.gov/cancersselected/ChromophobeRenalCellCarcinoma

5. At the time that Patient E first presented to Respondent and other doctors at the Burzynski Clinic, Patient E was not in a medical condition requiring emergency or intensive medical care.

6. Patient E sought treatment by Respondent with antineoplastons in part due to reading or viewing statements referenced in Allegation No. G(5 and 6) herein below.

7. At the time of the initial meeting with Respondent, Patient E had not had a recent biopsy showing malignancy. Respondent did not obtain the results of more recent biopsy before initiating treatment of Patient E. Respondent's order and/or recommendation of initiating anti-cancer treatment before obtaining a more recent confirming biopsy or other relevant confirming test violated the standard of care.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D), 190.8(1)(G), and 190.8(1)(H); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

8. Respondent was one of Patient E's treating physicians throughout Patient E's treatment directed by physicians working at the Burzynski Clinic. Patient E's treatment was initiated at the Burzynski Clinic pursuant to Respondent's recommendations and direction.

9. At the time the Patient E first met with Respondent and the other employees of the Burzynski Clinic, Respondent allowed Lourdes DeLeon and Larissa Tikhomirova, persons who are not licensed physicians or health care providers in Texas or elsewhere in the United States of America, to represent to Patient E that Lourdes DeLeon and Larissa Tikhomirova were licensed medical doctors practicing medicine in Texas. Respondent continued to allow Patient E

to believe that Lourdes DeLeon and Larissa Tikhomirova were licensed medical doctors practicing medicine in Texas throughout Patient E's treatment by the Burzynski Clinic.

10. Respondent and the other Burzynski Clinic employees under Respondent's supervision and control referred to Lourdes DeLeon and Larissa Tikhomirova as "Dr. DeLeon" and "Dr. Larissa" in Patient E's presence. Respondent reasonably knew that Lourdes DeLeon and Larissa Tikhomirova signed documents, many of which were also signed by Patient E , in manners that identified themselves as medical doctors. Patient E reasonably believed that Lourdes DeLeon and Larissa Tikhomirova were medical doctors licensed to practice medicine in the state of Texas. Respondent was responsible for the false, misleading and deceptive representation to Patient E that Lourdes DeLeon and Larissa Tikhomirova were medical doctors licensed to practice medicine in the state of Texas.

Violation

Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct that is likely to deceive or defraud the public, as provided by Section 164.053, or injure the public.

11. Lourdes DeLeon and Larissa Tikhomirova, persons who are not licensed physicians or health care providers in Texas or elsewhere in the United States of America, performed medical tasks that constituted the practice of medicine in the state of Texas in the evaluation, diagnosis and treatment of Patient E.

a. Evaluation of Patient E's medical condition on or about September 7, 2011, September 8, 2011, September 9, 2011, September 10, 2011, September 11, 2011, September 12, 2011, September 13, 2011, September 14, 2011, September 15, 2011, and September 16, 2011.

b. Diagnosis of Patient E's medical condition on or about September 7, 2011, September 8, 2011, September 9, 2011, September 10, 2011, September 11, 2011, September 12, 2011, September 13, 2011, September 14, 2011, September 15, 2011, and September 16, 2011.

c. Making recommendations for treatment of Patient E's medical condition on or about September 7, 2011, September 8, 2011, September 9, 2011, September 10, 2011, September 11, 2011, September 12, 2011, September 13, 2011, September 14, 2011, September 15, 2011, and September 16, 2011.

d. Making decisions regarding the treatment of Patient E's medical condition on or about September 7, 2011, September 8, 2011, September 9, 2011,

September 10, 2011, September 11, 2011, September 12, 2011, September 13, 2011, September 14, 2011, September 15, 2011, and September 16, 2011.

12. Respondent directed and/or reasonably knew of and allowed Lourdes DeLeon and Larissa Tikhomirova, persons who are not licensed physicians or health care providers in Texas or elsewhere in the United States of America, to perform medical tasks that constituted the practice of medicine in the state of Texas in the evaluation, diagnosis and treatment of Patient E. Respondent's direction, delegation and/or allowance of Lourdes DeLeon and Larissa Tikhomirova's performance of medical tasks that constituted the practice of medicine in the state of Texas in the evaluation, diagnosis and treatment of Patient E constituted inadequate supervision and delegating a person to perform medical tasks for which that person was not appropriately trained and/or licensed.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); (3) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician; and (4) Section 164.053(a)(9) of the Act, delegation of professional medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not qualified by training, experience or licensure to perform the responsibility or acts.

13. After Respondent made recommendations for Patient E's treatment, Respondent continued to be Patient E's treating physician throughout Patient A's treatment by the Burzynski Clinic. Patient E was also treated by physicians who were working at the Burzynski Clinic and physicians were working in collaboration the Burzynski Clinic. All of these other physicians treated Patient E under Respondent's direction and control while Respondent was Patient E's treating physician.

14. Respondent initiated treatment of Patient E without adequately documenting Respondent's medical rationale and discussion with Patient E about Respondent's pathologic diagnosis. Respondent initiated treatment of Patient E without adequately documenting

Respondent's analysis of genomic screening and discussion with Patient E about Respondent's genotypic and phenotypic diagnosis.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; and (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C).

15. Respondent recommendation and/or direction to initiate anti-cancer treatment of Patient E without pathologic documentation of malignancy in Respondent's medical records for Patient E violated the standard of care and standards of adequate documentation.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D), 190.8(1)(G); 190.8(1)(H); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

16. Patient E had initially informed the Burzynski Clinic that Patient E wanted "antineoplaston" therapy rather than classic or other chemotherapy treatments. SH made clear his intention to not accept therapy similar to that previously received (Votrient, a tyrosine kinase inhibitor), due to the severity of the side effects he experienced with that agent. At the time that Patient E presented to Respondent at the Burzynski Clinic on or about September 7, 2011, Patient E informed Respondent that Patient E wanted "antineoplaston" therapy rather than classic or other chemotherapy treatments.

17. Respondent informed Patient E that he would be considered for antineoplaston therapy. At the time Respondent made this representation, Respondent failed to inform Patient E that Respondent was not going to assist Patient E in obtaining access to being treated with antineoplaston therapy. Therefore, Respondent's representation was false, misleading and deceptive.

Violation

Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct that is likely to deceive or defraud the public, as provided by Section 164.053, or injure the public.

18. After assuring Patient E that he would obtain the treatment he desired, Respondent and the employees of the Burzynski Clinic under his supervision and control directed Patient E to pay a large sum of money on retainer for the anti-cancer therapy by the Burzynski Clinic.

19. After assuring Patient E that he would obtain the treatment he desired, and after Patient E paid a large sum of money on retainer for anti-cancer therapy by the Burzynski Clinic, Respondent recommended and directed treatments for Patient E that did not include "antineoplaston" therapy. Respondent recommended and directed treatments with these other substances without adequately explaining to Patient E the difference in safety and efficacy between the therapy requested by Patient E and the therapy provided by Respondent and the employees of the Burzynski Clinic under his supervision and control.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C), 190.8(1)(H), and 190.8(1)(I); and (3) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

20. Respondent recommended and directed that Patient E start treatment with phenylbutyrate, Afinitor, Sutent[26], and Xgeva[27].

21. Respondent and other health care providers under Respondent's direction and control treated Patient E without regard to the potential combined toxicities of drugs used pursuant to Respondent's recommendations and directions. Respondent and other health care providers under Respondent's direction and control referenced the case reports of other physicians not associated with the Burzynski Clinic as support for combined use of the drugs

[26] Anti-cancer medication
[27] Anti-cancer medication

listed in Allegation No. E.19 above. In those referenced case reports of physicians not associated with the Burzynski Clinic, however, those drugs were only used individually or in other combinations besides the combinations of drugs used for Patient E by Respondent and other health care providers under Respondent's direction and control. In this regard, Respondent and other health care providers under Respondent's direction and control violated the standard of care for reasons including:

a. Patient E suffered considerable toxicity with prior Votrient therapy, but Respondent urged SH to simultaneously take both a tyrosine kinase inhibitor (Sutent) and an mTOR inhibitor (Afinitor).

b. Both agents have a high propensity to cause diarrhea and mucositis. Patient E's pre-existing renal disease put him at significant increased risk of renal toxicity from the therapy recommended and directed by Respondent.

c. Respondent violated the standard of care by failing to have an adequate medical rationale for this simultaneous use of these agents in anti-cancer therapy.

d. Respondent violated standards of adequate documentation by failing to document an adequate medical rationale for this simultaneous use of these agents in anti-cancer therapy.

e. Respondent also failed to adequately inform Patient E of this increased risk.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

22. Patient E discontinued treatment by the Burzynski Clinic after one week due to his belief that Respondent and the persons under Respondent's supervision, direction and control had been dishonest and deceptive with him about the treatment available to him at the Burzynski Clinic. Respondent's evaluation, diagnosis and treatment of Patient E ended on or about September 15, 2011.

23. The Burzynski Clinic, under Respondent's direction and control, billed Patient B and Patient B's healthcare insurance carrier for services and charges that were medically unnecessary and not adequately supported by documentation including the following:

a.	September 7, 2011	
	Genetic Examination	$40.00
	VEG F Vascular Endothelial	$400.00
	Her-2/Neu	$350.00
	Dr. Yi/Prolonged Ser. W/O Contact	$350.00
	Molecular Diagnostics	$600.00
	Dr. Yi/Prolonged Ser. W/O Contact	$150.00
	Molecular Diagnostics	$40.00
	Dr. Yi/Office Consultation	$1,000.00
	Molecular Mutation Identify	$200.00
	EGFR Epidermal Growth Factor	$400.00
b.	September 8, 2011	
	Dr. Yi/Office/Outpatient Visit	$100.00
	Measure Blood Oxygen Level	$35.00
	Dr. Burzynski/Nutritional Medical Therapy	$300.00
	Sodium Phenylbutyrate 500 mg	$60.00
c.	September 9, 2011	
	Dr. Yi/Office/Outpatient Visit	$100.00
	Measure Blood Oxygen Level	$35.00
	Sodium Phenylbutyrate 500 mg	$120.00
d.	September 10, 2011	
	Medical services after hours	$95.00
	Sodium Phenylbutyrate 500 mg	$180.00
	Measure Blood Oxygen Level	$35.00
	Dr. Yi/Office/Outpatient Visit	$75.00
e.	September 11, 2011	
	Medical services after hours	$95.00
	Dr. Yi/Office/Outpatient Visit	$75.00
	Sodium Phenylbutyrate 500 mg	$240.00
	Measure Blood Oxygen Level	$35.00
f.	September 12, 2011	
	Sodium Phenylbutyrate 500 mg	$300.00
g.	September 13, 2011	
	Therapeutic or Diagnostic Inj	$100.00
	Sodium Phenylbutyrate 500 mg	$360.00
	Xgeva 1 mg	$3,300.00
h.	September 14, 2011	
	Afinitor	$473.88
	Sodium Phenylbutyrate 500 mg	$360.00
	Dr. Yi/Office/Outpatient Visit	$100.00
	Measure Blood Oxygen Level	$35.00
i.	September 15, 2011	
	Lipid Panel	$50.00
	Measure Blood Oxygen Level	$35.00

	LD Lactate Dehydrogenase	$25.00
	Dr. Burzynski/Office/Outpatient Visit	$125.00
	Monthly Case Management	$4,500.00
	Sodium Phenylbutyrate 500 mg	$360.00
	Mg Magnesium	$50.00
j.	September 16, 2011	
	Dr. Burzynski/Office/Outpatient Visit	$125.00
	Measure Blood Oxygen Level	$35.00

24. Many of the improper charges for evaluation, diagnosis and treatment of Patient A by the Burzynski Clinic were done at the direction and control of Respondent, and were for medically unnecessary services. Many of the improper charges for evaluation, diagnosis and treatment of Patient A by the Burzynski Clinic under the direction and control of Respondent were not adequately supported by documentation. These improper charges constituted violations of the Act and Board Rules.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); (3) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; (4) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper; and (5) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

25. Respondent inadequately supervised the activities of Burzynski Clinic employees acting under Respondent's supervision who were evaluating and treating Patient E. Respondent's inadequate supervision included failure to document his review of documents related to evaluation, diagnosis and treatment of Patient E.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); and (3) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

26. Respondent delegated professional medical responsibility or acts to employees of the Burzynski Clinic regarding the evaluation and treatment of Patient E when Respondent knew or had reason to know that those employees were not qualified by training, experience or licensure to perform the responsibility or acts. Those acts included the following:

a. Evaluation of Patient E's medical condition on or about September 7, 2011, September 8, 2011, September 9, 2011, September 10, 2011, September 11, 2011, September 12, 2011, September 13, 2011, September 14, 2011, September 15, 2011, and September 16, 2011.

b. Diagnosis of Patient E's medical condition on or about September 7, 2011, September 8, 2011, September 9, 2011, September 10, 2011, September 11, 2011, September 12, 2011, September 13, 2011, September 14, 2011, September 15, 2011, and September 16, 2011.

c. Making recommendations for treatment of Patient E's medical condition on or about September 7, 2011, September 8, 2011, September 9, 2011, September 10, 2011, September 11, 2011, September 12, 2011, September 13, 2011, September 14, 2011, September 15, 2011, and September 16, 2011.

d. Making decisions regarding the treatment of Patient E's medical condition on or about September 7, 2011, September 8, 2011, September 9, 2011, September 10, 2011, September 11, 2011, September 12, 2011, September 13, 2011, September 14, 2011, September 15, 2011, and September 16, 2011.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); (3) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician; and (3) Section 164.053(a)(9) of the Act, delegation of professional medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not qualified by training, experience or licensure to perform the responsibility or acts.

27. Respondent's recommendation and/or direction for the treatment of Patient E with various substances referenced above in Allegation No. E.19 violated the standard of care.

a. Review of prior history and records of prior treatment and related conditions.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by their failure to attempt to obtain and to review prior medical records for Patient E at the time that Respondent initially recommended and/or directed anti-cancer treatment for Patient E. These failures to obtain and review medical records of prior evaluation and treatment included:

a. Medical Records of Patient E relating to evaluation and treatment for metastatic renal cell carcinoma from early 2002 through 2003.
b. Medical Records of Patient E relating to evaluation and treatment for metastatic renal cell carcinoma from January 2009 through December 29, 2010.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document attempts to obtain and review prior medical records for Patient E at the time that Respondent initially recommended and/or directed anti-cancer treatment for Patient E.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); and 190.8(1)(C); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

b. Physical examination.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate physical examination of Patient E at the time that Respondent recommended and/or directed anti-cancer treatment for Patient E. These failures to perform an adequate physical examination included:

a. After the initial office visit physical examination on or about September 7, 2001, during the time period of office visits in September 2011.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standards of adequate documentation by failure to document performance of an adequate physical examination of Patient E at the time that Respondent recommended and/or directed anti-cancer treatment for Patient E.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; and (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

c. Mental status examination.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate mental status examination at the time that Respondent recommended and/or directed anti-cancer treatment for Patient E. These failures to perform an adequate mental status examination included:

a. After the initial office visit physical examination on or about September 7, 2001, during the time period of office visits in September 2011.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate mental status examination at the time that Respondent recommended and/or directed anti-cancer treatment for Patient E. Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate mental status examination after initiating recommended anti-cancer treatments for Patient E. These failures to perform the elements of an adequate mental status examination included failure to determine:

a. the patient's ability to identify themselves;
b. the patient's awareness of their surroundings;
c. whether the patient is aware of what they are being seen for;
d. the patient's ability to make decisions for themselves;
e. the patient's ability to understand the directions for taking the medications;
f. the patient's awareness of the risks of the medications;
g. patient's frame of mind and general psychiatric condition, such as anxiety or depression, if any.

3) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document a mental status examination at the time that Respondent recommended and/or directed anti-cancer treatment for Patient E.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); and 190.8(1)(C); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

d. Treatment plan.

1) The inadequate treatment plan documented by Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision for Patient E at the time that Respondent recommended and/or directed anti-cancer treatment for Patient E. Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision failed to include the following elements of a treatment plan that are required by the standard of care:

a. Objectives to measure treatment effectiveness, including a method for determining effectiveness of polypharmacy, when more than one substance is used to treat a patient during the same time period;
b. Objectives for alleviation of symptoms;
c. Monitoring of objectives of treatment effectiveness;
d. Monitoring of alleviation of symptoms;
e. Monitoring of side effects of treatment; and
f. Dosages and instructions for treatment medications.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document an adequate treatment plan at the time that Respondent recommended and/or directed anti-cancer treatment for Patient E.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); and 190.8(1)(C); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

e. Over-all medical rationale.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to have an adequate medical rationale for evaluation, diagnosis and treatment at the time of Respondent recommendations and/or direction of anti-cancer therapy for Patient E.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document an adequate medical rationale for evaluation, diagnosis and treatment at the time of Respondent's recommendations and/or direction of anti-cancer therapy for Patient E.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); and 190.8(1)(C); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

f. Informed consent.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to adequately discuss about the risks and benefits of the treatment with Patient E at the time of Respondent recommendations and/or direction of anti-cancer therapy for Patient E.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standards of adequate documentation by failure to document an adequate discussion about the risks and benefits of the treatment with Patient E at the time of Respondent's recommendations and/or direction of anti-cancer therapy for Patient E.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

g. Discussion of treatment alternatives.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to adequately discuss alternative anti-cancer treatments with Patient E at the time of Respondent recommendations and/or direction of anti-cancer therapy for Patient E.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document alternative treatments discussed with Patient E at the time of Respondent's recommendations and/or direction of anti-cancer therapy for Patient E.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D), 190.8(1)(H); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

28. Respondent had an ownership interest in the pharmacy that dispensed phenylbutyrate and other drugs provided by the pharmacy owned by Respondent. Respondent's failure to disclose this ownership interest to Patient E violated the Act and Board Rules.

Violation

Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility.

29. Respondent billed multiple charges, as set forth in Section E.23 above, to Patient E for which there is no adequate description of the service or product in the medical record. Respondent also, therefore, billed for these services and/or products improperly.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); (3) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; (4) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper.

30. Respondent directed the unnecessary measurement of Patient E's oxygen saturation. Patient E had no significant pulmonary disease, and the medial records are without justification for this testing. Respondent also, therefore, billed for these services and/or products improperly.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); (3) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; and (4) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper.

31. Respondent directed the unnecessary and costly laboratory testing for measures that are without demonstrable benefit to Patient E, including, at the initial visit, an echocardiogram, an assay of plasma VEGF, serum EGFR, and her-2. Respondent also, therefore, billed for these services and/or products improperly.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); (3) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; and (4) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper.

32. Respondent directed and charged Patient E for unnecessary and costly imaging studies for Patient E that were medically unnecessary. Respondent directed that an ECHO cardiogram be performed when one had been done just two months after a prior adequate study completed at Patient E's home. PET scanning was ordered by Respondent despite adequate imaging (MRI) having been done within the prior two months. The PET study, in fact, demonstrated no change from the prior MRI.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); (3) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; (4) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper.

33. Respondent had an ownership interest in the laboratory that performed the tests that Respondent directed. Respondent did not disclose this ownership interest to Patient E.

Violation

(1) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility.

34. Respondent failed to adequately inform Patient E of the risks and benefits of the therapies that Respondent recommended and/or directed for Patient E. Respondent's failure violated the Act and Board Rules.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

35. Respondent's recommendations and/or directions for the treatment of Patient E was non-therapeutic treatment.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

F. Specific Allegations: Violation of Standard of Care Patient F

1. In September 2009, Patient F received a diagnosis of pathologically benign hyperplastic fundic polyps. Imaging studies revealed a suspicious poorly marginated pancreatic mass and metastases to the liver. A biopsy performed on September 25, 2009, revealed poorly differentiated metastatic adenocarcinoma.

2. Patient F declined a local physician's recommendation of chemotherapy.

3. Patient F sought treatment at the Respondent's clinic and met with Respondent on or about October 8, 2009.

4. At the time that Patient F first presented to Respondent and other doctors at the Burzynski Clinic, Patient F was not in a medical condition requiring emergency or intensive medical care.

5. Patient F sought treatment by Respondent with antineoplastons in part due to reading or viewing statements referenced in Allegation No. G(5 and 6) herein below.

6. Patient F had a history of taking Valtrex[28], but did not present with a medical condition for which Valtrex is an FDA-approved treatment. Respondent recommended and directed that Patient F be treated with Valtrex. The treatment of Patient F with Valtrex by Respondent and persons under Respondent's direction and control violated the standard of care and was non-therapeutic treatment. Respondent and persons under Respondent's direction and control failed to adequately document the medical rationale for treating Patient F with Valtrex.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

7. Respondent was one of Patient F's treating physicians throughout Patient F's treatment directed by physicians working at the Burzynski Clinic. Patient F's treatment was initiated at the Burzynski Clinic pursuant to Respondent's recommendations and direction. Although Robert Weaver, M.D. was the physician who attended Patient F, Respondent directed the elements of the treatment plan regarding testing, imaging and therapy.

[28] Anti-viral medication

8. At the time the Patient F first met with Respondent and the other employees of the Burzynski Clinic, Respondent allowed Larissa Tikhomirova, a person who is not a licensed physician or health care provider in Texas or elsewhere in the United States of America, to represent to Patient F that Larissa Tikhomirova was a licensed medical doctor practicing medicine in Texas. Respondent continued to allow Patient F and Patient F's wife to believe that Larissa Tikhomirova was a licensed medical doctor practicing medicine in Texas throughout Patient F's treatment at the Burzynski Clinic.

9. Respondent and the other Burzynski Clinic employees under Respondent's supervision and control referred to Larissa Tikhomirova as "Dr. Tikhomirova" in Patient F's and Patient F's wife's presence. Respondent reasonably knew that Larissa Tikhomirova signed documents, many of which were also signed by Patient F and Patient F's wife, in manners that identified himself as a medical doctor. Patient F and Patient F's wife reasonably believed that Larissa Tikhomirova was a medical doctor licensed to practice medicine in the state of Texas. Respondent was responsible for the false, misleading and deceptive representation to Patient F and Patient F's wife that Larissa Tikhomirova was a medical doctor licensed to practice medicine in the state of Texas.

Violation

Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct that is likely to deceive or defraud the public, as provided by Section 164.053, or injure the public.

10. Larissa Tikhomirova, a person who is not a licensed physician or health care provider in Texas or elsewhere in the United States of America, performed medical tasks that constituted the practice of medicine in the state of Texas in the evaluation, diagnosis and treatment of Patient F.

a. Evaluation of Patient F's medical condition on or about October 8, 2009, October 9, 2009, October 10, 2009, October 11, 2009, October 12, 2009, October 13, 2009, October 14, 2009, October 15, 2009, October 16, 2009, October 17, 2009, October 19, 2009, October 31, 2009, and October 11, 2009.

b. Diagnosis of Patient F's medical condition on or about October 8, 2009, October 9, 2009, October 10, 2009, October 11, 2009, October 12, 2009, October

13, 2009, October 14, 2009, October 15, 2009, October 16, 2009, October 17, 2009, October 19, 2009, October 31, 2009, and October 11, 2009.

c. Making recommendations for treatment of Patient F's medical condition on or about October 8, 2009, October 9, 2009, October 10, 2009, October 11, 2009, October 12, 2009, October 13, 2009, October 14, 2009, October 15, 2009, October 16, 2009, October 17, 2009, October 19, 2009, October 31, 2009, and October 11, 2009.

d. Making decisions regarding the treatment of Patient F's medical condition on or about October 8, 2009, October 9, 2009, October 10, 2009, October 11, 2009, October 12, 2009, October 13, 2009, October 14, 2009, October 15, 2009, October 16, 2009, October 17, 2009, October 19, 2009, October 31, 2009, and October 11, 2009.

11. Respondent directed and/or reasonably knew of and allowed Larissa Tikhomirova, a person who is not a licensed physician or health care provider in Texas or elsewhere in the United States of America, to perform medical tasks that constituted the practice of medicine in the state of Texas in the evaluation, diagnosis and treatment of Patient F. Respondent's direction, delegation and/or allowance of Larissa Tikhomirova's performance of medical tasks that constituted the practice of medicine in the state of Texas in the evaluation, diagnosis and treatment of Patient F constituted inadequate supervision and delegating a person to perform medical tasks for which that person was not appropriately trained and/or licensed.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); (3) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician; and (4) Section 164.053(a)(9) of the Act, delegation of professional medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not qualified by training, experience or licensure to perform the responsibility or acts.

12. After Respondent made recommendations for Patient F's treatment, Respondent continued to be Patient F's treating physician throughout Patient F's treatment by the Burzynski Clinic. Patient F was also treated by physicians who were working at the Burzynski Clinic and physicians were working in collaboration the Burzynski Clinic. All of these other physicians treated Patient F under Respondent's direction and control while Respondent was Patient F's treating physician.

13. Respondent initiated treatment of Patient F without adequately documenting Respondent's medical rationale and discussion with Patient F about Respondent's pathologic diagnosis. Respondent initiated treatment of Patient F without adequately documenting Respondent's analysis of genomic screening and discussion with Patient F about Respondent's genotypic and phenotypic diagnosis.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; and (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C).

14. Respondent recommendation and/or direction to initiate anti-cancer treatment of Patient F without pathologic documentation of malignancy in Respondent's medical records for Patient F violated the standard of care and standards of adequate documentation.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D), 190.8(1)(G); 190.8(1)(H); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

15. Patient F had initially informed the Burzynski Clinic that Patient F wanted "antineoplaston" therapy rather than classic or other chemotherapy treatments. At the time that Patient F presented to Respondent at the Burzynski Clinic on or about October 8, 2009, Patient F informed Respondent that Patient F wanted "antineoplaston" therapy rather than classic or other chemotherapy treatments.

16. Respondent informed Patient F that he would be considered for antineoplaston therapy. At the time Respondent made this representation, Respondent failed to inform Patient F that he did not meet the criteria for inclusion in a clinical study of antineoplaston therapy. Therefore, Respondent's representation was false, misleading and deceptive.

Violation

Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct that is likely to deceive or defraud the public, as provided by Section 164.053, or injure the public.

17. After assuring Patient F that he would obtain the treatment he desired, Respondent and the employees of the Burzynski Clinic under his supervision and control directed Patient F to pay a large sum of money on retainer for the anti-cancer therapy by the Burzynski Clinic.

18. After assuring Patient F that he would obtain the treatment he desired, and after Patient F paid a large sum of money on retainer for anti-cancer therapy by the Burzynski Clinic, Respondent recommended and directed treatments for Patient F that did not include "antineoplaston" therapy. Respondent recommended and directed treatments with these other substances without adequately explaining to Patient F the difference in safety and efficacy between the therapy requested by Patient F and the therapy provided by Respondent and the employees of the Burzynski Clinic under his supervision and control.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C), 190.8(1)(H), and 190.8(1)(I); and (3) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

19. Respondent recommended and directed that Patient F start treatment with phenylbutyrate. Although Dr. Weaver included this recommendation on the initial treatment plan for Patient F, Respondent initiated this recommendation and directed this treatment.

20. Respondent recommended and directed that Patient F start various other substances for treatment, including Xeloda, Avastin, Nexavar, Zolinza, Rapamune[29], Sutent, Afinitor, Xeloda, gencitabine[30]; Xgeva and Valtrex. Although Dr. Weaver included these

[29] Anti-cancer medication
[30] Anti-cancer medication

recommendations on the treatment plans for Patient F, Respondent initiated these recommendations and directed this treatment.

21. Patient F soon experienced multiple side effects from the substances that Respondent recommended and directed for treatment of Patient E.

22. Patient F canceled Respondent's treatments as of mid-November 2009.

23. Respondent's evaluation, diagnosis and treatment of Patient F ended in mid-November 2009.

24. The Burzynski Clinic, under Respondent's direction and control, billed Patient F and Patient F's healthcare insurance carrier for services and charges that were medically unnecessary and not adequately supported by documentation including the following:

a.	October 8, 2009	
	Dr. Burzynski/ Prolonged Eval. & Mgmt before or	$350.00
	Dr. Burzynski/ Prolonged Eval. & Mgmt each add	$150.00
	Dr. Burzynski/ Consultation - Comprehensive	$1,000.00
	Her-2/Neu	$350.00
	EGFR Epidermal Growth Factor	$400.00
	VEG F Vascular Endothelial	$400.00
	Genetic Examination	$40.00
b.	October 9, 2009	
	Dr. Burzynski/Follow up Visit	$125.00
	Measure Blood Oxygen Level	$35.00
	Sodium Phenylbutyrate 500 mg	$60.00
	Add supply – supplement	$360.00
c.	October 10, 2009	
	Sodium Phenylbutyrate 500 mg	$120.00
	Rapamune 1 mg	$738.90
d.	October 11, 2009	
	Sodium Phenylbutyrate 500 mg	$180.00
	Zolinza 100 mg	$5,646.00
e.	October 12, 2009	
	Dr. Burzynski/Follow up Visit	$125.00
	Measure Blood Oxygen Level	$35.00
	Sodium Phenylbutyrate 500 mg	$240.00

f.	October 13, 2009	
	Dr. Burzynski/Follow up Visit	$125.00
	Measure Blood Oxygen Level	$35.00
	Sodium Phenylbutyrate 500 mg	$300.00
	Xeloda 500 mg	$2,385.60
g.	October 14, 2009	
	Dr. Burzynski/Follow up Visit	$125.00
	Measure Blood Oxygen Level	$35.00
	Sodium Phenylbutyrate 500 mg	$180.00
	Nexavar 200 mg	$8,419.80
h.	October 15, 2009	
	Lithium Batteries AA	$14.22
	MG Magnesium	$50.00
	Lipid Profile	$50.00
	Lactate Deydrogenase	$25.00
	Avastin 10 mg	$2,915.00
	Dexamethasone	$4.80
	Chemotherapy administration IV	$198.00
	Dr. Burzynski/Follow up Visit	$125.00
	Measure Blood Oxygen Level	$35.00
	Sodium Phenylbutyrate 500 mg	$360.00
i.	October 16, 2009	
	Dr. Burzynski/Follow up Visit	$125.00
	Measure Blood Oxygen Level	$35.00
	Sodium Phenylbutyrate 500 mg	$360.00
	Office outpatient visit, New	$410.00
j.	October 18, 2009	
	Sodium Phenylbutyrate 500 mg	$720.00
k.	October 19, 2009	
	Sodium Phenylbutyrate 500 mg	$360.00
	Dr. Burzynski/Follow up Visit	$200.00
	Measure Blood Oxygen Level	$35.00
	Sodium Phenylbutyrate 500 mg	$360.00
l.	October 31, 2009	
	Sodium Phenylbutyrate 500 mg	$4,320.00
m.	November 11, 2009	
	Sodium Phenylbutyrate 500 mg	$3,960.00

25. Many of the improper charges for evaluation, diagnosis and treatment of Patient A by the Burzynski Clinic were done at the direction and control of Respondent, and were for medically unnecessary services. Many of the improper charges for evaluation, diagnosis and treatment of Patient A by the Burzynski Clinic under the direction and control of Respondent

were not adequately supported by documentation. These improper charges constituted violations of the Act and Board Rules.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); (3) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; (4) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper; and (5) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

26. Respondent inadequately supervised the activities of Burzynski Clinic employees acting under Respondent's supervision who were evaluating and treating Patient F. Respondent's inadequate supervision included failure to document his review of documents related to evaluation, diagnosis and treatment of Patient F.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); and (3) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

27. Respondent delegated professional medical responsibility or acts to employees of the Burzynski Clinic regarding the evaluation and treatment of Patient F when Respondent knew or had reason to know that those employees were not qualified by training, experience or licensure to perform the responsibility or acts. Those acts included the following:

a. Evaluation of Patient F's medical condition on or about October 8, 2009, October 9, 2009, October 10, 2009, October 11, 2009, October 12, 2009, October 13, 2009, October 14, 2009, October 15, 2009, October 16, 2009, October 17, 2009, October 19, 2009, October 31, 2009, and October 11, 2009.

b. Diagnosis of Patient F's medical condition on or about October 8, 2009, October 9, 2009, October 10, 2009, October 11, 2009, October 12, 2009, October 13, 2009, October 14, 2009, October 15, 2009, October 16, 2009, October 17, 2009, October 19, 2009, October 31, 2009, and October 11, 2009.

c. Making recommendations for treatment of Patient F's medical condition on or about October 8, 2009, October 9, 2009, October 10, 2009, October 11, 2009, October 12, 2009, October 13, 2009, October 14, 2009, October 15, 2009, October 16, 2009, October 17, 2009, October 19, 2009, October 31, 2009, and October 11, 2009.

d. Making decisions regarding the treatment of Patient F's medical condition on or about October 8, 2009, October 9, 2009, October 10, 2009, October 11, 2009, October 12, 2009, October 13, 2009, October 14, 2009, October 15, 2009, October 16, 2009, October 17, 2009, October 19, 2009, October 31, 2009, and October 11, 2009.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); and (3) Section 164.053(a)(9) of the Act, delegation of professional medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not qualified by training, experience or licensure to perform the responsibility or acts.

29. Respondent's recommendation and/or direction for the treatment of Patient F with various substances referenced above in Allegation No. F.20 violated the standard of care.

a. Physical examination.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate physical examination of Patient F at the time that Respondent recommended and/or directed anti-cancer treatment for Patient F. These failures to perform an adequate physical examination included:

a. After the initial office visit physical examination on or about October 8, 2009, during the time period of office visits in October 2009.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standards of adequate documentation by failure to document performance of an adequate physical examination of Patient F at the time that Respondent recommended and/or directed anti-cancer treatment for Patient F.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; and (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A);

190.8(1)(B); 190.8(1)(C); 190.8(1)(D); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

b. Mental status examination.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate mental status examination at the time that Respondent recommended and/or directed anti-cancer treatment for Patient F. These failures to perform an adequate mental status examination included:

a. After the initial office visit physical examination on or about October 8, 2009, during the time period of office visits in October 2009.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate mental status examination at the time that Respondent recommended and/or directed anti-cancer treatment for Patient F. Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate mental status examination after initiating recommended anti-cancer treatments for Patient F. These failures to perform the elements of an adequate mental status examination included failure to determine:

a. the patient's ability to identify themselves;
b. the patient's awareness of their surroundings;
c. whether the patient is aware of what they are being seen for;
d. the patient's ability to make decisions for themselves;
e. the patient's ability to understand the directions for taking the medications;
f. the patient's awareness of the risks of the medications;
g. patient's frame of mind and general psychiatric condition, such as anxiety or depression, if any.

3) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to

adequately document a mental status examination at the time that Respondent recommended and/or directed anti-cancer treatment for Patient F.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); and 190.8(1)(C); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

c. Treatment plan.

1) The inadequate treatment plan documented by Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision for Patient F at the time that Respondent recommended and/or directed anti-cancer treatment for Patient F. Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision failed to include the following elements of a treatment plan that are required by the standard of care:

a. Objectives to measure treatment effectiveness, including a method for determining effectiveness of polypharmacy, when more than one substance is used to treat a patient during the same time period;
b. Objectives for alleviation of symptoms;
c. Monitoring of objectives of treatment effectiveness;
d. Monitoring of alleviation of symptoms;
e. Monitoring of side effects of treatment; and
f. Dosages and instructions for treatment medications.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document an adequate treatment plan at the time that Respondent recommended and/or directed anti-cancer treatment for Patient F.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); and 190.8(1)(C); (3)

Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

d. Over-all medical rationale.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to have an adequate medical rationale for evaluation, diagnosis and treatment at the time of Respondent recommendations and/or direction of anti-cancer therapy for Patient F.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document an adequate medical rationale for evaluation, diagnosis and treatment at the time of Respondent's recommendations and/or direction of anti-cancer therapy for Patient F.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); and 190.8(1)(C); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

e. Informed consent.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to adequately discuss about the risks and benefits of the treatment with Patient F at the time of Respondent recommendations and/or direction of anti-cancer therapy for Patient F.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standards of adequate documentation by failure to

document an adequate discussion about the risks and benefits of the treatment with Patient F at the time of Respondent's recommendations and/or direction of anti-cancer therapy for Patient F.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

f. Discussion of treatment alternatives.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to adequately discuss alternative anti-cancer treatments with Patient F at the time of Respondent recommendations and/or direction of anti-cancer therapy for Patient F.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document alternative treatments discussed with Patient F at the time of Respondent's recommendations and/or direction of anti-cancer therapy for Patient F.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D), 190.8(1)(H); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (5) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

30. Respondent had an ownership interest in the pharmacy that dispensed phenylbutyrate and other drugs provided by the pharmacy owned by Respondent. Respondent's failure to disclose this ownership interest to Patient F violated the Act and Board Rules.

Violation

Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility.

31. Respondent billed multiple charges, as set forth in Section F.24 above, to the patient for which there is no adequate description of the service or product in the medical record. Respondent also, therefore, billed for these services and/or products improperly.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); (3) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; and (4) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper.

32. Respondent directed the unnecessary measurement of Patient F's oxygen saturation. Patient F had no significant pulmonary disease, and the medial records are without justification for this testing. Respondent also, therefore, billed for these services and/or products improperly.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); (3) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; and (4) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper.

33. Respondent directed the unnecessary and costly laboratory testing for measures that are without demonstrable benefit to Patient F, including, at the initial visit, an

echocardiogram, an assay of plasma VEGF, serum EGFR, and her-2. Respondent also, therefore, billed for these services and/or products improperly.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); (3) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; and (4) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper.

34. Respondent had an ownership interest in the laboratory that performed the tests that Respondent directed. Respondent did not disclose this ownership interest to Patient F.

Violation

Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility.

35. Respondent failed to adequately inform Patient F of the risks and benefits of the therapies that Respondent recommended and/or directed for Patient F. Respondent's failure violated the Act and Board Rules.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

36. Respondent's recommendations and/or directions for the treatment of Patient F was non-therapeutic treatment.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C);

190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

37. Respondent and other health care providers under Respondent's direction and control treated Patient F without regard to the potential combined toxicities of drugs used pursuant to Respondent's recommendations and directions. Respondent and other health care providers under Respondent's direction and control referenced the case reports of other physicians not associated with the Burzynski Clinic as support for combined use of the drugs recommended and administered to Patient F. In those referenced case reports of physicians not associated with the Burzynski Clinic, however, those drugs were only used individually or in other combinations besides the combinations of drugs used for Patient F by Respondent and other health care providers under Respondent's direction and control. In this regard, Respondent and other health care providers under Respondent's direction and control violated the standard of care for reasons including:

a. Patient F suffered considerable toxicity affects.

b. Respondent violated the standard of care by failing to have an adequate medical rationale for this simultaneous use of these agents in anti-cancer therapy.

c. Respondent violated standards of adequate documentation by failing to document an adequate medical rationale for this simultaneous use of these agents in anti-cancer therapy.

d. Respondent also failed to adequately inform Patient F of this increased risk.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

G. Specific Allegations: Violation of Standard of Care Patient G

1. In July 2012, Patient G received a diagnosis of suprasellar mass brain cancer and malignant astrocytoma of the optic nerve based on imaging studies and biopsy.

2. After Patient G experienced side effects from taking the anti-cancer medication Avastin, she declined a local physician's recommendation to begin radiation therapy and taking the anti-cancer medication Temodar.

3. Patient G sought treatment at the Respondent's clinic and met with Respondent on or about August 31, 2012.

4. At the time that Patient G first presented to Respondent and other doctors at the Burzynski Clinic, Patient G was not in a medical condition requiring emergency or intensive medical care.

5. Patient G sought treatment by Respondent with antineoplastons in part due to reading or viewing statements referenced in Allegation No. G(5 and 6) herein below.

6. Respondent and the other Burzynski Clinic employees under Respondent's supervision and control made false, misleading and deceptive statements about the safety and efficacy of antineoplastons and the elements of the Burzynski Research Institute's clinical study program for administration of antineoplastons for which Patient G and Patient G's healthcare healthcare insurance carrier would be charged.

Violation

Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct that is likely to deceive or defraud the public, as provided by Section 164.053, or injure the public.

7. At the time of the initial meeting with Respondent, Respondent assured Patient G that she would be admitted into the Burzynski Research Institute's clinical study program for administration of antineoplastons.

8. After assuring Patient G that she would obtain the treatment she desired, Respondent and the employees of the Burzynski Clinic under his supervision and control directed Patient G to pay a large sum of money on retainer for the anti-cancer therapy by the Burzynski Clinic and the Burzynski Research Institute.

9. Prior to September 12, 2012, Patient G's treatment was initiated at the Burzynski Clinic pursuant to Respondent's recommendations and direction.

10. On or about September 12, 2012, the Burzynski Research Institute's clinical study program for administration of antineoplastons admitted Patient G into one of the Phase 2 clinical studies subject to a study protocol.

11. Respondent was the sponsor and principal investigator for the Burzynski Research Institute's clinical study program for administration of antineoplastons.

12. Pursuant to federal regulations and the Burzynski Research Institute's agreement with the FDA regarding the clinical study program for administration of antineoplastons, Respondent had responsibilities to comply with those regulations and that agreement and to follow the approved protocols for each approved clinical study.

13. As principal investigator of the Phase 2 clinical study to which Patient G was admitted, Respondent's conduct of administering and/or providing investigational agents related to the treatment of Patient G by the Burzynski Clinic was the practice of medicine in the state of Texas as defined by Section 151.002(13) of the Act.

14. Respondent failed to comply with federal regulations, the Burzynski Research Institute's agreement with the FDA regarding the clinical study program for administration of antineoplastons and the approved protocols for the approved clinical study in which Patient G was enrolled. Such failures included Respondent's direction and allowance for Patient G to be charged for the antineoplaston therapy and Respondent's direction and allowance for these

charges to be characterized as something else, "chemo prolong infuse". This characterization was false, misleading and deceptive.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D), 190.8(1)(G), and 190.8(1)(H); and (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; (4) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper; and (5) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code;

15. In September 2012, Respondent recommended and directed antineoplastons to be administered and dispensed by the Burzynski Clinic to Patient G.

16. At the time the Patient G first met with Respondent and the other employees of the Burzynski Clinic, Respondent allowed Sheryll Acelar, a person who is not a licensed physician or health care provider in Texas or elsewhere in the United States of America, to represent to Patient G that Sheryll Acelar was a licensed medical doctor practicing medicine in Texas. Respondent continued to allow Patient G and Patient G's mother to believe that Sheryll Acelar was a licensed medical doctor practicing medicine in Texas throughout Patient G's treatment at the Burzynski Clinic.

17. Respondent and the other Burzynski Clinic employees under Respondent's supervision and control referred to Sheryll Acelar as "Dr. Acelar" in Patient G's and Patient G's mother's presence. Respondent reasonably knew that Sheryll Acelar signed documents, many of which were also signed by Patient G and Patient G's mother, in manners that identified himself as a medical doctor. Patient G and Patient G's mother reasonably believed that Sheryll Acelar was a medical doctor licensed to practice medicine in the state of Texas. Respondent was responsible for the false, misleading and deceptive representation to Patient G and Patient G's

mother that Sheryll Acelar was a medical doctor licensed to practice medicine in the state of Texas.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); (3) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct that is likely to deceive or defraud the public, as provided by Section 164.053, or injure the public; (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician; and (5) Section 164.053(a)(9) of the Act, delegation of professional medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not qualified by training, experience or licensure to perform the responsibility or acts.

18. Sheryll Acelar, a person who is not a licensed physician or health care provider in Texas or elsewhere in the United States of America, performed medical tasks that constituted the practice of medicine in the state of Texas in the evaluation, diagnosis and treatment of Patient G.

a. Evaluation of Patient G's medical condition on or about August 31, 2012, September 10, 2012, September 12, 2012, September 13, 2012, September 2012, September 15, 2012, September 16, 2012, September 17, 2012, September 17, 2012, September 18, 2012, September 19, 2012, September 20, 2012, September 22, 2012, September 23, 2012, September 24, 2012, September 29, 2012, September 30, 2012, October 3, 2012, October 4, 2012, October 5, 2012, October 6, 2012, October 8, 2012, October 9, 2012, October 10, 2012, October 11, 2012, October 13, 2012, October 15, 2012, October 16, 2012, October 17, 2012, October 18, 2012, October 23, 2012, October 24, 2012, October 25, 2012, October 26, 2012, October 27, 2012, November 1, 2012, November 5, 2012, November 6, 2012, November 7, 2012, November 8, 2012, November 9, 2012, November 13, 2012, and November 14, 2012.

b. Diagnosis of Patient G's medical condition on or about August 31, 2012, September 10, 2012, September 12, 2012, September 13, 2012, September 2012, September 15, 2012, September 16, 2012, September 17, 2012, September 17, 2012, September 18, 2012, September 19, 2012, September 20, 2012, September 22, 2012, September 23, 2012, September 24, 2012, September 29, 2012, September 30, 2012, October 3, 2012, October 4, 2012, October 5, 2012, October 6, 2012, October 8, 2012, October 9, 2012, October 10, 2012, October 11, 2012, October 13, 2012, October 15, 2012, October 16, 2012, October 17, 2012, October 18, 2012, October 23, 2012, October 24, 2012, October 25, 2012, October 26, 2012, October 27, 2012, November 1, 2012, November 5, 2012, November 6, 2012, November 7, 2012, November 8, 2012, November 9, 2012, November 13, 2012, and November 14, 2012.

c. Making recommendations for treatment of Patient G's medical condition on or about August 31, 2012, September 10, 2012, September 12, 2012, September 13, 2012, September 2012, September 15, 2012, September 16, 2012, September 17, 2012, September 17, 2012, September 18, 2012, September 19, 2012, September 20, 2012, September 22, 2012, September 23, 2012, September 24, 2012, September 29, 2012, September 30, 2012, October 3, 2012, October 4, 2012, October 5, 2012, October 6, 2012, October 8, 2012, October 9, 2012, October 10, 2012, October 11, 2012, October 13, 2012, October 15, 2012, October 16, 2012, October 17, 2012, October 18, 2012, October 23, 2012, October 24, 2012, October 25, 2012, October 26, 2012, October 27, 2012, November 1, 2012, November 5, 2012, November 6, 2012, November 7, 2012, November 8, 2012, November 9, 2012, November 13, 2012, and November 14, 2012.

d. Making decisions regarding the treatment of Patient G's medical condition on or about August 31, 2012, September 10, 2012, September 12, 2012, September 13, 2012, September 2012, September 15, 2012, September 16, 2012, September 17, 2012, September 17, 2012, September 18, 2012, September 19, 2012, September 20, 2012, September 22, 2012, September 23, 2012, September 24, 2012, September 29, 2012, September 30, 2012, October 3, 2012, October 4, 2012, October 5, 2012, October 6, 2012, October 8, 2012, October 9, 2012, October 10, 2012, October 11, 2012, October 13, 2012, October 15, 2012, October 16, 2012, October 17, 2012, October 18, 2012, October 23, 2012, October 24, 2012, October 25, 2012, October 26, 2012, October 27, 2012, November 1, 2012, November 5, 2012, November 6, 2012, November 7, 2012, November 8, 2012, November 9, 2012, November 13, 2012, and November 14, 2012.

19. Respondent directed and/or reasonably knew of and allowed Sheryll Acelar, a person who is not a licensed physician or health care provider in Texas or elsewhere in the United States of America, to perform medical tasks that constituted the practice of medicine in the state of Texas in the evaluation, diagnosis and treatment of Patient G. Respondent's direction, delegation and/or allowance of Sheryll Acelar's performance of medical tasks that constituted the practice of medicine in the state of Texas in the evaluation, diagnosis and treatment of Patient G constituted inadequate supervision and delegating a person to perform medical tasks for which that person was not appropriately trained and/or licensed.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); (3) Section

164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician; and (4) Section 164.053(a)(9) of the Act, delegation of professional medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not qualified by training, experience or licensure to perform the responsibility or acts.

20. After Respondent made recommendations for and directed for Patient G's treatment, Respondent continued to be Patient G's treating physician throughout Patient G's treatment by the Burzynski Clinic. Patient G was also treated by physicians who were working at the Burzynski Clinic and physicians were working in collaboration the Burzynski Clinic. All of these other physicians treated Patient G under Respondent's direction and control while Respondent was Patient G's treating physician.

21. In mid-November 2012, Patient G decided to stop Respondent's recommended treatments and the antineoplaston therapy after imaging confirmed that the tumor had increased in size while she was taking the antineoplastons and after she experienced significant side effects from the medication and complications from the manner of administration.

22. Respondent's evaluation, diagnosis and treatment of Patient G ended at the end of November 2012.

23. The Burzynski Clinic, under Respondent's direction and control, billed Patient B and Patient B's healthcare insurance carrier for services and charges that were medically unnecessary and not adequately supported by documentation including the following:

a.	<u>August 31, 2012</u>	
	Dr. Valladares/Office Consultation	$1,250.00
b.	<u>September 10, 2012</u>	
	Pregnancy Test	$30.00
	Pt Prothrombin Time with INR (duplicated)	$25.00
c.	<u>September 12, 2012</u>	
	LD Lactate Dehydrogenase	$25.00
	Group Health Education	$60.00
	Dexamethasone	$12.50
	Measure Blood Oxygen Level	$35.00

	External ambulatory infuse pump	$5,500.00
	Chemo, IV Push, Single Drug	$170.00
	Lipid Panel	$50.00
	Special Reports and Treatment	$400.00
	Patient Education Materials	$35.00
	MG Magnesium	$50.00
	Chemo Prolong Infuse w/p	$395.00
d.	September 13, 2012	
	Group Health Education	$60.00
	Measure Blood Oxygen Level	$35.00
	Dr. Marquis/Office/Outpatient Visit	$125.00
	Chemo Prolong Infuse w/p	$395.00
e.	September 14, 2012	
	Chemo Prolong Infuse w/p	$395.00
	Lipid Panel	$50.00
	LD Lactate Dehydrogenase	$25.00
	Group Health Education	$60.00
	MG Magnesium	$50.00
	Measure Blood Oxygen Level	$35.00
	Electrolyte Panel	$25.00
	Dr. Valladares/Office/Outpatient Visit	$125.00
f.	September 15, 2012	
	Chemo Prolong Infuse w/p	$395.00
	Medical Services after Hrs.	$95.00
	Electrolyte Panel	$25.00
	Measure Blood Oxygen Level	$35.00
	Dr. Burzynski/Office/Outpatient Visit	$75.00
g.	September 16, 2012	
	Chemo Prolong Infuse w/p	$395.00
	Measure Blood Oxygen Level	$35.00
	Medical Services after Hrs.	$95.00
	Dr. Burzynski/Office/Outpatient Visit	$75.00
h.	September 17, 2012	
	UA Urinalysis, Non-Auto W/	$25.00
	Measure Blood Oxygen Level	$35.00
	Group Health Education	$60.00
	MG Magnesium	$50.00
	LD Lactate Dehydrogenase	$25.00
	Chemo Prolong Infuse w/p	$395.00
	Lipid Panel	$50.00
	Dr. Marquis/Office/Outpatient Visit	$125.00
i.	September 18, 2012	
	Dr. Burzynski/Office/Outpatient Visit	$125.00
	Group Health Education	$60.00

	Measure Blood Oxygen Level	$35.00
	Nutritional Medical Therapy	$300.00
	Chemo Prolong Infuse w/p	$395.00
j.	September 19, 2012	
	LD Lactate Dehydrogenase	$25.00
	Lipid Panel	$50.00
	Group Health Education	$60.00
	MG Magnesium	$50.00
	Dr. Marquis/Office/Outpatient Visit	$125.00
	Chemo Prolong Infuse w/p	$395.00
k.	September 20, 2012	
	Electrolyte Panel	$25.00
	Dr. Marquis/Office/Outpatient Visit	$125.00
	Chemo Prolong Infuse w/p	$395.00
	Group Health Education	$60.00
	Measure Blood Oxygen Level	$35.00
l.	September 21, 2012	
	Group Health Education	$60.00
	Chemo Prolong Infuse w/p	$395.00
	UA Urinalysis, Non-Auto W/	$25.00
	Measure Blood Oxygen Level	$35.00
	Dr. Marquis/Office/Outpatient Visit	$125.00
m.	September 22, 2012	
	Chemo Prolong Infuse w/p	$395.00
	Measure Blood Oxygen Level	$35.00
	Dr. Burzynski/Office/Outpatient Visit	$75.00
n.	September 23, 2012	
	Dr. Burzynski/Office/Outpatient Visit	$75.00
	Measure Blood Oxygen Level	$35.00
	Medical Services after Hours	$95.00
o.	September 24, 2012	
	Lipid Panel	$50.00
	Measure Blood Oxygen Level	$35.00
	UA Urinalysis, Non-Auto W/	$25.00
	Electrolyte Panel	$25.00
	LD Lactate Dehydrogenase	$25.00
	Dr. Marquis/Office/Outpatient Visit	$125.00
p.	September 25, 2012	
	Continue Flo Solution Kit	$268.00
	Y adapter 2-way	$285.48
	Body Guard Dual Tubing/Car	$3,360.00
	Sodium Chloride Flush 5 cc	$358.80
	Dr. Burzynski/Office/Outpatient Visit	$200.00
q.	September 29, 2012	

	Chemo Prolong Infuse w/p	$395.00
r.	September 30, 2012	
	Chemo Prolong Infuse w/p	$395.00
s.	October 1, 2012	
	Chemo Prolong Infuse w/p	$395.00
t.	October 2, 2012	
	Chemo Prolong Infuse w/p	$395.00
u.	October 3, 2012	
	Chemo Prolong Infuse w/p	$395.00
v.	October 4, 2012	
	Chemo Prolong Infuse w/p	$395.00
x.	October 5, 2012	
	Chemo Prolong Infuse w/p	$395.00
y.	October 6, 2012	
	Chemo Prolong Infuse w/p	$395.00
z.	October 8, 2012	
	Chemo Prolong Infuse w/p	$395.00
aa.	October 9, 2012	
	Chemo Prolong Infuse w/p	$395.00
bb.	October 10, 2012	
	Chemo Prolong Infuse w/p	$395.00
cc.	October 11, 2012	
	Chemo Prolong Infuse w/p	$395.00
dd.	October 12, 2012	
	Chemo Prolong Infuse w/p	$395.00
ee.	October 13, 2012	
	Chemo Prolong Infuse w/p	$395.00
ff.	October 15, 2012	
	Chemo Prolong Infuse w/p	$395.00
gg.	October 16, 2012	
	Chemo Prolong Infuse w/p	$395.00
hh.	October 17, 2012	
	Chemo Prolong Infuse w/p	$395.00
ii.	October 18, 2012	
	Chemo Prolong Infuse w/p	$395.00
jj.	October 19, 2012	
	Chemo Prolong Infuse w/p	$395.00
kk.	October 23, 2012	
	Chemo Prolong Infuse w/p	$395.00
ll.	October 24, 2012	
	Chemo Prolong Infuse w/p	$395.00
mm.	October 25, 2012	
	Chemo Prolong Infuse w/p	$395.00
nn.	October 26, 2012	

	Chemo Prolong Infuse w/p	$395.00
oo.	October 27, 2012	
	Chemo Prolong Infuse w/p	$395.00
pp.	November 1, 2012	
	Chemo Prolong Infuse w/p	$395.00
	Y adapter 2-way	$219.60
	Body Guard Dual Tubing/Car	$1,890.00
	Sodium Chloride Flush 5 cc	$358.80
	Dr. Burzynski/Office/Outpatient Visit	$200.00
qq.	November 5, 2012	
	Chemo Prolong Infuse w/p	$395.00
rr.	November 6, 2012	
	Chemo Prolong Infuse w/p	$395.00
ss.	November 7, 2012	
	Chemo Prolong Infuse w/p	$395.00
tt.	November 8, 2012	
	Chemo Prolong Infuse w/p	$395.00
uu.	November 9, 2012	
	Chemo Prolong Infuse w/p	$395.00
vv.	November 12, 2012	
	Chemo Prolong Infuse w/p	$395.00
xx.	November 13, 2012	
	Chemo Prolong Infuse w/p	$395.00
yy.	November 14, 2012	
	Chemo Prolong Infuse w/p	$395.00

24. Many of the improper charges for evaluation, diagnosis and treatment of Patient A by the Burzynski Clinic were done at the direction and control of Respondent, and were for medically unnecessary services. Many of the improper charges for evaluation, diagnosis and treatment of Patient A by the Burzynski Clinic under the direction and control of Respondent were not adequately supported by documentation. These improper charges constituted violations of the Act and Board Rules.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); (3) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; (4) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party

payer that the licensee knew or should have known was improper; and (5) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

25. Respondent inadequately supervised the activities of Burzynski Clinic employees acting under Respondent's supervision who were evaluating and treating Patient G. Respondent's inadequate supervision included failure to document his review of documents related to evaluation, diagnosis and treatment of Patient G.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); and (3) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

26. Respondent delegated professional medical responsibility or acts to employees of the Burzynski Clinic regarding the evaluation and treatment of Patient G when Respondent knew or had reason to know that those employees were not qualified by training, experience or licensure to perform the responsibility or acts. These acts included the following:

a. Evaluation of Patient G's medical condition on or about August 31, 2012, September 10, 2012, September 12, 2012, September 13, 2012, September 2012, September 15, 2012, September 16, 2012, September 17, 2012, September 17, 2012, September 18, 2012, September 19, 2012, September 20, 2012, September 22, 2012, September 23, 2012, September 24, 2012, September 29, 2012, September 30, 2012, October 3, 2012, October 4, 2012, October 5, 2012, October 6, 2012, October 8, 2012, October 9, 2012, October 10, 2012, October 11, 2012, October 13, 2012, October 15, 2012, October 16, 2012, October 17, 2012, October 18, 2012, October 23, 2012, October 24, 2012, October 25, 2012, October 26, 2012, October 27, 2012, November 1, 2012, November 5, 2012, November 6, 2012, November 7, 2012, November 8, 2012, November 9, 2012, November 13, 2012, and November 14, 2012.

b. Diagnosis of Patient G's medical condition on or about August 31, 2012, September 10, 2012, September 12, 2012, September 13, 2012, September 2012, September 15, 2012, September 16, 2012, September 17, 2012, September 17, 2012, September 18, 2012, September 19, 2012, September 20, 2012, September 22, 2012, September 23, 2012, September 24, 2012, September 29, 2012, September 30, 2012, October 3, 2012, October 4, 2012, October 5, 2012, October 6, 2012, October 8, 2012, October 9, 2012, October 10, 2012, October 11, 2012, October 13, 2012, October 15, 2012, October 16, 2012, October 17, 2012,

October 18, 2012, October 23, 2012, October 24, 2012, October 25, 2012, October 26, 2012, October 27, 2012, November 1, 2012, November 5, 2012, November 6, 2012, November 7, 2012, November 8, 2012, November 9, 2012, November 13, 2012, and November 14, 2012.

c. Making recommendations for treatment of Patient G's medical condition on or about August 31, 2012, September 10, 2012, September 12, 2012, September 13, 2012, September 2012, September 15, 2012, September 16, 2012, September 17, 2012, September 17, 2012, September 18, 2012, September 19, 2012, September 20, 2012, September 22, 2012, September 23, 2012, September 24, 2012, September 29, 2012, September 30, 2012, October 3, 2012, October 4, 2012, October 5, 2012, October 6, 2012, October 8, 2012, October 9, 2012, October 10, 2012, October 11, 2012, October 13, 2012, October 15, 2012, October 16, 2012, October 17, 2012, October 18, 2012, October 23, 2012, October 24, 2012, October 25, 2012, October 26, 2012, October 27, 2012, November 1, 2012, November 5, 2012, November 6, 2012, November 7, 2012, November 8, 2012, November 9, 2012, November 13, 2012, and November 14, 2012.

d. Making decisions regarding the treatment of Patient G's medical condition on or about August 31, 2012, September 10, 2012, September 12, 2012, September 13, 2012, September 2012, September 15, 2012, September 16, 2012, September 17, 2012, September 17, 2012, September 18, 2012, September 19, 2012, September 20, 2012, September 22, 2012, September 23, 2012, September 24, 2012, September 29, 2012, September 30, 2012, October 3, 2012, October 4, 2012, October 5, 2012, October 6, 2012, October 8, 2012, October 9, 2012, October 10, 2012, October 11, 2012, October 13, 2012, October 15, 2012, October 16, 2012, October 17, 2012, October 18, 2012, October 23, 2012, October 24, 2012, October 25, 2012, October 26, 2012, October 27, 2012, November 1, 2012, November 5, 2012, November 6, 2012, November 7, 2012, November 8, 2012, November 9, 2012, November 13, 2012, and November 14, 2012.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); and (3) Section 164.053(a)(9) of the Act, delegation of professional medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not qualified by training, experience or licensure to perform the responsibility or acts.

27. Respondent's recommendation and/or direction for the treatment of Patient G with antineoplastons referenced above in Allegation No. G.15 violated the standard of care.

a. Physical examination.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate physical examination of Patient G at the time that Respondent recommended and/or directed anti-cancer treatment for Patient G. These failures to perform an adequate physical examination included:

a. At and after the initial office visit physical examination on or about August 27, 2012 during the time period of office visits in September 2012.
b. During the two month time period of October and November 2011.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standards of adequate documentation by failure to document performance of an adequate physical examination of Patient G at the time that Respondent recommended and/or directed anti-cancer treatment for Patient G.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; and (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

b. Mental status examination.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate mental status examination at the time that Respondent recommended and/or directed anti-cancer treatment for Patient G. These failures to perform an adequate mental status examination included:

a. At and after the initial office visit physical examination on or about August 27, 2012 during the time period of office visits in September 2012.
b. During the two month time period of October and November 2011.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate

mental status examination at the time that Respondent recommended and/or directed anti-cancer treatment for Patient G. Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform an adequate mental status examination after initiating recommended anti-cancer treatments for Patient G. These failures to perform the elements of an adequate mental status examination included failure to determine:

a. the patient's ability to identify themselves;
b. the patient's awareness of their surroundings;
c. whether the patient is aware of what they are being seen for;
d. the patient's ability to make decisions for themselves;
e. the patient's ability to understand the directions for taking the medications;
f. the patient's awareness of the risks of the medications;
g. patient's frame of mind and general psychiatric condition, such as anxiety or depression, if any.

3) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document a mental status examination at the time that Respondent recommended and/or directed anti-cancer treatment for Patient G.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); and 190.8(1)(C); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

c. Treatment plan.

1) The inadequate treatment plan documented by Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision for Patient G at the time that Respondent recommended and/or directed anti-cancer treatment for Patient G. Respondent and Burzynski Clinic employees acting under Respondent's direction

and supervision failed to include the following elements of a treatment plan that are required by the standard of care:

a. Objectives to measure treatment effectiveness, including a method for determining effectiveness of polypharmacy, when more than one substance is used to treat a patient during the same time period;
b. Objectives for alleviation of symptoms;
c. Monitoring of objectives of treatment effectiveness;
d. Monitoring of alleviation of symptoms;
e. Monitoring of side effects of treatment; and
f. Dosages and instructions for treatment medications.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document an adequate treatment plan at the time that Respondent recommended and/or directed anti-cancer treatment for Patient G.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); and 190.8(1)(C); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

d. Over-all medical rationale.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to have an adequate medical rationale for evaluation, diagnosis and treatment at the time of Respondent recommendations and/or direction of anti-cancer therapy for Patient G.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to

adequately document an adequate medical rationale for evaluation, diagnosis and treatment at the time of Respondent's recommendations and/or direction of anti-cancer therapy for Patient G.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); and 190.8(1)(C); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

e. Informed consent.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to adequately discuss about the risks and benefits of the treatment with Patient G at the time of Respondent recommendations and/or direction of anti-cancer therapy for Patient G.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standards of adequate documentation by failure to document an adequate discussion with Patient G at the time of Respondent's recommendations and/or direction of anti-cancer therapy for Patient G.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

f. Discussion of treatment alternatives.

1) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to adequately discuss alternative anti-cancer treatments with Patient G at the time of Respondent recommendations and/or direction of anti-cancer therapy for Patient G.

2) Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated standards of adequate documentation by failure to adequately document alternative treatments discussed with Patient G at the time of Respondent's recommendations and/or direction of anti-cancer therapy for Patient G.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D), 190.8(1)(H); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

28. Respondent had an ownership interest in the pharmacy that dispensed antineoplastons provided by the pharmacy owned by Respondent. Respondent's failure to disclose this ownership interest to Patient G violated the Act and Board Rules.

Violation

Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility.

29. Respondent billed multiple charges, as set forth in Section G.23 above, to Patient G for which there is no adequate description of the service or product in the medical record. Respondent also, therefore, billed for these services and/or products improperly.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); (3) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; (4) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically

unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper.

30. Respondent directed the unnecessary measurement of Patient G's oxygen saturation. Patient G had no significant pulmonary disease, and the medial records are without justification for this testing. Respondent also, therefore, billed for these services and/or products improperly.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); (3) Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; (4) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper.

31. Respondent had an ownership interest in the laboratory that performed the tests that Respondent directed. Respondent did not disclose this ownership interest to Patient G. Respondent had an ownership interest in the pharmacy that dispensed antineoplastons and other drugs that Respondent directed be administered to Patient G. Respondent did not disclose this ownership interest to Patient G.

Violation

Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility.

32. Respondent failed to adequately inform Patient G of the risks and benefits of the therapies that Respondent recommended and/or directed for Patient G. Respondent's failure violated the Act and Board Rules.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or

nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

33. Respondent's recommendations and/or directions for the treatment of Patient G was non-therapeutic treatment.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C); 190.8(1)(G); 190.8(1)(H); 190.8(1)(I); (3) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

34. When initiating treatment, Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision allowed Patient G's parent to open an account whereby the public could read about Patient G's medical and financial crisis and contribute money to that account. Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision reasonably were aware that the website that hosted this contribution account would provide any donations directly to the Burzynski Clinic to pay for the costs of Patient G's treatment and that such costs had already been paid in advance by Patient G's parent.

35. When Patient G's parent had a billing dispute with Respondent and the Burzynski Clinic, Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision rejected donations and refused to accept those donations as a credit on Patient G's account at the Burzynski Clinic. Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision returned all of those donations to the website that had received the donations from donors as an intermediary.

36. Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision informed Patient G's parent that since Patient G's parent had already paid in advance and did not have a balance owed at the time of the donations, the Burzynski Clinic

would not accept donations on Patient G's account. Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision returned a significant amount of donations that were made to help Patient G out with the cost of treatment by Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision.

37 Additionally, Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision received significant reimbursement payments from an insurance company on Patient G's behalf. Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision refused to refund Patient G for those insurance benefits paid.

38. Respondent was principal investigator and sponsor of the clinical study of antineoplaston therapy for Patient G that commenced on or about September 12, 2012.

39. This clinical study was subject to federal law, federal regulations, the BRI-IRB investigation plan and the study protocols submitted for the study that included Patient G. FDA regulations 21 CFR 312.3(b), 21 CFR 312.50 and 21 CFR 312.60 applied to the clinical study in which Patient G was enrolled.

40. The federal regulatory requirements for approval of single patient protocols for Phase 1 or Phase 2 clinical studies require that the investigator ensure that risks to patient/subjects are minimized and reasonable in relation to anticipated benefits.

41. Respondent, as principal investigator and as sponsor of the clinical study of antineoplaston therapy for Patient G, had a responsibility to ensure that risks to Patient G were minimized and reasonable in relation to anticipated benefits.

42. Ensuring that risks to patient/subjects are minimized and reasonable in relation to anticipated benefits requires (1) review of the subject's medical records (history and physical

examination) and (2) clarifying any outstanding issues with respect to the suitability of treating the patient/subject prior to granting institutional review board approval.

43. Respondent, as principal investigator and as sponsor of the clinical study of antineoplaston therapy for Patient G, failed to do the following to protect Patient G who was a patient/human subject in the clinical study of antineoplastons; (1) Respondent failed to take adequate measures to minimize risks to Patient G; and (2) Respondent failed to ensure that the risks to Patient G were reasonable in relation to anticipated benefits and the importance of the generalizable knowledge that may be expected to result.

44. Respondent's failure, as principal investigator and as sponsor of the clinical study of antineoplaston therapy for Patient G, to ensure that risks to Patient G were minimized and reasonable in relation to anticipated benefits violated the standard of care, federal regulations, the Act and Board Rules.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); (3) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct; (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.50-59, and 21 CFR 312.60-71; (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician; and (5) Section 164.053(a)(9) of the Act, delegation of professional medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not qualified by training, experience or licensure to perform the responsibility or acts.

45. Respondent as principal investigator and as sponsor initiated treatment of Patient G as a human subject in a clinical study of antineoplastons Respondent, as principal investigator, was required to report all adverse events that occurred for Patient G.

46. Respondent, as a sponsor and as an investigator, had a responsibility to submit informed consent documents for Patient G that complied with federal regulations.

47. Respondent, as a sponsor and as an investigator, failed to report all adverse events for Patient G accurately and failed to provide adequate informed consent documents for Patient G related to the clinical study. Respondent's failures violated the standard of care, federal regulations, the Act and Board Rules.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); (3) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct; (3) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.50-59, and 21 CFR 312.60-71; (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician; and (5) Section 164.053(a)(9) of the Act, delegation of professional medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not qualified by training, experience or licensure to perform the responsibility or acts.

48. Only physicians who had clinical expertise necessary to make the required information evaluation of potential risks and anticipated benefits could professionally evaluate applicant patients regarding enrollment criteria and protocols related to medical condition, risks of treatments and benefits of treatments.

49. Respondent, as principal investigator and as sponsor, allowed persons who did not have the necessary clinical expertise to make an evaluation of the potential risks and anticipated benefits of antineoplaston therapy for Patient G.

50. Respondent, as principal investigator and as sponsor, allowed persons who did not have the necessary clinical expertise to make an evaluation of the potential risks and anticipated benefits of antineoplaston therapy for Patient G was a violation of the standard of care, federal regulations, the Act and Board Rules.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); (3) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct; (3) Section 164.053(a)(1) of the Act,

commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.50-59, and 21 CFR 312.60-71; (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician; and (5) Section 164.053(a)(9) of the Act, delegation of professional medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not qualified by training, experience or licensure to perform the responsibility or acts.

51 Respondent, as principal investigator and as sponsor of the clinical study of antineoplaston therapy for Patient G, failed to provide an adequate clinical protocol for Patient G.

52 The investigational plans for clinical study of antineoplastons in which Patient G was enrolled required Respondent, as sponsor and as investigator: (1) to only report therapeutic responses based on how the Patient G's tumors responded to the study drug; (2) to report all adverse response events for Patient G; (3) to ensure that persons under his direction and control providing care to the patients in a clinical study are adequately trained or retrained after adverse events, such as overdose of the investigational new drug.

53 After Respondent was notified of adverse events for Patient G, he failed to adequately train or re-train those persons under his direction and control to prevent additional adverse events.

54 Respondent, as sponsor and as investigator, was required by federal regulations to consider and report the effect of corticosteroids on Patient G's responses to the investigational new drug.

55 Ensuring that protocols were followed to isolate the impact of corticosteroids on Patient G's tumor response was crucial to the Respondent's responsibility to ensure that complete and accurate data obtained regarding the safety, efficacy and benefits of the study drug to Patient G.

56 Respondent, as sponsor and as investigator, provided inaccurate reports of Patient G's tumor response while Patient G was receiving corticosteroids during the time period for which the tumor response was measured.

57 Patient G was receiving corticosteroids under Respondent's recommendations and direction that exceeded those dosages needed to maintain physiologic levels.

58 Respondent failed to assess Patient G's tumor response in accordance with the protocol requirements. This failure jeopardized Patient G's safety and welfare and raises concerns about the validity and integrity of the data collected in the clinical study.

59 Respondent's failure to ensure that protocols were followed constitutes a violation of federal regulations, the Act and Board Rules.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); (3) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct; (3) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.50-59, and 21 CFR 312.60-71; (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician; and (5) Section 164.053(a)(9) of the Act, delegation of professional medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not qualified by training, experience or licensure to perform the responsibility or acts.

60. Respondent, as a sponsor-investigator of a clinical study, was and continues to be required to ensure that patients in the clinical studies were provided informed consent in accordance with federal regulations.

61. The consent forms that Respondent directed for use in Patient G's clinical study were inadequate and violated federal regulations, particularly due to the lack of a statement informing the patient of any additional costs.

62 Failure to provide Patient G with information regarding any additional costs prior to obtaining her informed consent denied Patient G the opportunity to make an informed decision regarding their participation in the clinical investigation.

63 Respondent only presented a billing agreement to applicant Patient G after she had already consented to participate in the clinical studies. Respondent's failure to obtain adequate informed consent prior to initiation of treatment with antineoplastons constituted a violation of federal regulations, the Act and Board Rules.

64 Respondent's failure to maintain adequate and accurate medical records for Patient G in that clinical study violated federal regulations, the Act and Board Rules.

Violations

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct; (3) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.50-59, and 21 CFR 312.60-71; (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician; and (5) Section 164.053(a)(9) of the Act, delegation of professional medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not qualified by training, experience or licensure to perform the responsibility or acts.

G. **Violation of FDA Regulations Regarding Promotional Statements**

1. Prior to April 2005, an entity named the Burzynski Research Institute-Institutional Review Board ("BRI-IRB") was formed.

2. The Burzynski Research Institute initiated a series of agreements with the federal Food and Drug Administration for Respondent to conduct Phase 2 clinical studies of his investigational new drug, "antineoplastons." The sponsor of the clinical studies was and remains Respondent. The principal investigator of the clinical studies was and remains Respondent.

Respondent made the decision to conduct the clinical studies at the Burzynski Clinic. The clinical studies have been directed by Respondent. Respondent effectively controls the decision-making of the BRI-IRB.

3. At the time of the FDA agreement in or before April 2005 through June 13, 2013, 21 CFR 312.7(a) prohibited investigators from making "promotional" statements regarding investigational new drugs.

4. Respondent, as sponsor of the BRI-IRB clinical studies of antineoplastons, as principal investigator of the BRI-IRB clinical studies of antineoplastons, as 80% owner of the Burzynski Institute and as 100% owner of the Burzynski Clinic, failed to adequately and appropriately scrutinize statements and advertisements published on the website and failed to adhere to FDA regulations and appropriate ethical standards for truth in advertising.

5. Respondent directed that a website include statements and links to statements that the "Antineoplaston[31]" anti-cancer therapy: (a) was available for patients being treated by Respondent and other doctors at the Burzynski Clinic in Houston, Texas; (b) was relatively safe compared to other anti-cancer therapies; (c) was efficacious in treating many types of cancer; and (d) was more efficacious than other anti-cancer therapies. Antineoplastons are a substance created by Respondent and are not approved by the United States Food and Drug Administration (FDA) for use as a medication.

6. Respondent, in violation of FDA regulations for investigational new drugs, made or directed the making of the following statements for publication and advertising, including the statements published on a website and through links on that website, which were false, misleading and deceptive statements that the "Antineoplaston" anti-cancer therapy: (a) was available for patients being treated by Respondent and other doctors at the Burzynski Clinic in Houston, Texas; (b) was relatively safe compared to other anti-cancer therapies; and (c) was

[31]Anti-cancer treatment manufactured by Respondent; not approved by FDA for any use outside of approved phase 1 and phase 2 clinical studies.

efficacious in treating many types of cancer; and (d) was more efficacious than other anti-cancer therapies.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; 164.5, rules for advertising responsibility and 164.6, rules for statements on websites; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

7. In a letter dated October 18, 2012, the FDA required Respondent to cease the dissemination of improper promotional materials for antineoplastons.

8. The referenced materials that the FDA notified Respondent as being violative of federal regulations were found on multiple websites belonging to or sponsored by Respondent. At the time of the agreements for the clinical studies of antineoplastons pursuant to federal regulations, the Burzynski Clinic had an internet website at www.burzynskiclinic.com and the Burzynski Research Institute had a website at www.burzynskiresearch.com. Respondent made all final decisions about what was posted on these websites. Respondent had full professional responsibility for what was posted on these websites.

9. Statements and advertisements on Respondent's websites and/or websites sponsored by Respondent, violated the Federal Food, Drug, and Cosmetic Act and FDA regulation 21 CFR 312.7(a) which prohibits publication of promotional statements about investigational new drugs.

10. Since antineoplastons are investigational new drugs, their safety and efficacy are unproven at the current time; therefore, promoting them as safe and effective is a violation of FDA regulations.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; 164.5, rules for advertising responsibility and 164.6, rules for statements on websites; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

11. Respondent's advertisements violated federal law as they promoted these investigational agents as safe and effective, potentially causing consumers to have unjustified expectations about the safety and efficacy of the treatments.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; 164.5, rules for advertising responsibility and 164.6, rules for statements on websites; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

12. Furthermore, Respondent never informed consumers that antineoplastons have not been "proven" to cure cancer, and only stated that they were "not approved by the FDA."

13. Sometime between the date of the agreement with the FDA about the clinical studies and June 13, 2012, the following items were posted as material or hyperlinks on the www.burzynskiclinic.com website:

Postings:

A. "How do Antineoplastons work?" (heading)

"Antineoplastons act as molecular switches, which turn off live processes in abnormal cells and force them to die through apoptosis (programmed death of a cell) While they trigger the death of cancer cells, they do not inhibit cell growth. They specifically target cancer cells without harming healthy cells."

1) Respondent reasonably was aware at the time of the continued posting of these statements as of June 13, 2013, that insufficient scientific evidence existed to support these statements indicating (1) that antineoplastons selectively attacked, killed or inhibited the growth of cancer cells in the human body and (2) that antineoplastons did not harm healthy cells in the human body.

2) Respondent's posting of this statement was a publication.

3) Respondent's posting of this statement was an advertisement.

4) Respondent's publication of this statement was a promotional statement made in violation of 21 CFR 312.7(a).

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against

Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including , including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

5) Respondent publication of this statement is equivalent to publishing a statement that Antineoplastons have been proven safe for the treatment of cancers in humans.

6) Respondent publication of this statement is equivalent to publishing a statement that Antineoplastons have been proven effective for the treatment of cancers in humans.

7) Respondent's publication of this statement was an inaccurate statement.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

8) Respondent's publication of this statement was a misleading statement.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using

false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

9) Respondent's publication of this statement was a deceptive statement

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

B. "How do Antineoplastons work?" (heading)

"It is generally known that the cancerous process results from increased activity of oncogenes and decreased expression of tumor suppressor genes. Antineoplastons "turn on" tumor suppressor genes and "turn off" oncogenes restoring the proper balance in gene expression."

1) Respondent reasonably was aware at the time of the continued posting of these statements as of June 13, 2013, that insufficient scientific evidence existed to support these statements indicating (1) that antineoplastons selectively attacked, killed or inhibited the growth of cancer cells in the human body and (2) that antineoplastons did not harm healthy cells in the human body.

2) Respondent's posting of this statement was a publication.

3) Respondent's posting of this statement was an advertisement.

4) Respondent's publication of this statement was a promotional statement made in violation of 21 CFR 312.7(a).

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

5) Respondent publication of this statement is equivalent to publishing a statement that Antineoplastons have been proven safe for the treatment of cancers in humans.

6) Respondent publication of this statement is equivalent to publishing a statement that Antineoplastons have been proven effective for the treatment of cancers in humans.

7) Respondent's publication of this statement was an inaccurate statement.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is

false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

8) Respondent's publication of this statement was a misleading statement.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

9) Respondent's publication of this statement was a deceptive statement.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

Embedded videos posted:

C. "Tomorrow's Cancer Treatment Today"

Statement of Dr. Gregory Burzynski[32], Superimposed title "Gregory Burzynski, M.D., Senior Physician
"Antineoplastons are a group of peptides and amino acid derivatives originally discovered by my father, Dr. S. R. Burzynski. These are present in our blood, and in healthy tissue they are elevated, much more so than in people suffering cancer. They're molecular switches. They play a role on activating genes that are involved in the cancerous process, and also protecting you with genes that are causing cancer, so in essence, they have been shown to attack cancer cells but protect the other cells, so it's the best of both worlds."

1) Respondent reasonably was aware at the time of the continued posting of these statements as of June 13, 2013, that insufficient scientific evidence existed to support these statements indicating (1) that antineoplastons selectively attacked, killed or inhibited the growth of cancer cells in the human body and (2) that antineoplastons did not harm healthy cells in the human body.
2) Respondent's posting of this statement was a publication.
3) Respondent's posting of this statement was an advertisement.
4) Respondent's publication of this statement was a promotional statement made in violation of 21 CFR 312.7(a).

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

[32]Dr. Gregory "Greg" Burzynski, works at the Burzynski Clinic under Respondent's direction and control.

5) Respondent publication of this statement is equivalent to publishing a statement that Antineoplastons have been proven safe for the treatment of cancers in humans.

6) Respondent publication of this statement is equivalent to publishing a statement that Antineoplastons have been proven effective for the treatment of cancers in humans.

7) Respondent's publication of this statement was an inaccurate statement.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

8) Respondent's publication of this statement was a misleading statement.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is

connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

9) Respondent's publication of this statement was a deceptive statement.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

D. "Tomorrow's Cancer Treatment Today"; Scrolling superimposed sentence,

"Antineoplastons are multi-targeted cancer therapy and are targeting a multitude of genes involved in cancer."

1) Respondent reasonably was aware at the time of the continued posting of these statements as of June 13, 2013, that insufficient scientific evidence existed to support these statements indicating (1) that antineoplastons selectively attacked, killed or inhibited the growth of cancer cells in the human body and (2) that antineoplastons did not harm healthy cells in the human body.
2) Respondent's posting of this statement was a publication.
3) Respondent's posting of this statement was an advertisement.
4) Respondent's publication of this statement was a promotional statement made in violation of 21 CFR 312.7(a).

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine.

5) Respondent publication of this statement is equivalent to publishing a statement that Antineoplastons have been proven safe for the treatment of cancers in humans.

6) Respondent publication of this statement is equivalent to publishing a statement that Antineoplastons have been proven effective for the treatment of cancers in humans.

7) Respondent's publication of this statement was an inaccurate statement.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

8) Respondent's publication of this statement was a misleading statement.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine.

9) Respondent's publication of this statement was a deceptive statement.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

E. "Treatment at the Burzynski Clinic – KHOU Part 2"

Response of Dr. Sonali Patel to an interviewer's question about "Antineoplastons."

"They're building blocks, and basically the ones that Dr. Burzynski is talking about exist normally in our system and that's the reason why the drugs work without causing side effects. It's just that cancer patients lack them, and so what he is doing is putting it back into the system to help cure the cancer. And we find that these particular compounds have multiple targets; they're not working on one

particular pathway, but many pathways, which is what makes them a very effective anti-cancer medicine."

1) Respondent reasonably was aware at the time of the continued posting of these statements as of June 13, 2013, that insufficient scientific evidence existed to support these statements indicating (1) that antineoplastons selectively attacked, killed or inhibited the growth of cancer cells in the human body and (2) that antineoplastons did not harm healthy cells in the human body.

2) Respondent's posting of this statement was a publication.

3) Respondent's posting of this statement was an advertisement.

4) Respondent's publication of this statement was a promotional statement made in violation of 21 CFR 312.7(a).

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

5) Respondent publication of this statement is equivalent to publishing a statement that Antineoplastons have been proven safe for the treatment of cancers in humans.

6) Respondent publication of this statement is equivalent to publishing a statement that Antineoplastons have been proven effective for the treatment of cancers in humans.

7) Respondent's publication of this statement was an inaccurate statement.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

8) Respondent's publication of this statement was a misleading statement.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

9) Respondent's publication of this statement was a deceptive statement.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or

deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

F. Glioblastomas (subtitle)

"Glioblastomas, and it even in the laboratory, we see that these cells respond very very well to the compounds and this is the main treatment that is being regulated by the FDA for the approval is the brain tumors, and we have seen a lot of success with patients, as Dr. Burzynski will discuss, with this particular type of cancer."

1) Respondent reasonably was aware at the time of the continued posting of these statements as of June 13, 2013, that insufficient scientific evidence existed to support these statements indicating (1) that antineoplastons selectively attacked, killed or inhibited the growth of cancer cells in the human body and (2) that antineoplastons did not harm healthy cells in the human body.
2) Respondent's posting of this statement was a publication.
3) Respondent's posting of this statement was an advertisement.
4) Respondent's publication of this statement was a promotional statement made in violation of 21 CFR 312.7(a).

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of

the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

5) Respondent publication of this statement is equivalent to publishing a statement that Antineoplastons have been proven safe for the treatment of cancers in humans.
6) Respondent publication of this statement is equivalent to publishing a statement that Antineoplastons have been proven effective for the treatment of cancers in humans.
7) Respondent's publication of this statement was an inaccurate statement.
8) Respondent's publication of this statement was a misleading statement.
9) Respondent's publication of this statement was a deceptive statement

G. Response of Dr. Stansilaw Burzynski to question about "Antineoplastons."

"Certainly, well, in FDA controlled clinical trials, we are limited to the patients who cannot be helped with any other treatment, and we place emphasis on the worst possible type of cancer. For instance, inoperable brainstem malignant tumors, everybody dies from these tumors regardless of what kind of treatment is used, and most of the patients who are, mostly children, are dead within two years. Our survival for children in the age up to three years, is 50% at five years, which is remarkable. And, we have patients who are now surviving over twenty years without any sign of this type of cancer."

1) Respondent reasonably was aware at the time of the continued posting of these statements as of June 13, 2013, that insufficient scientific evidence existed to support these statements indicating (1) that antineoplastons selectively attacked, killed or inhibited the growth of cancer cells in the human body and (2) that antineoplastons did not harm healthy cells in the human body.
2) Respondent's posting of this statement was a publication.
3) Respondent's posting of this statement was an advertisement.

4) Respondent's publication of this statement was a promotional statement made in violation of 21 CFR 312.7(a)

5) Respondent publication of this statement is equivalent to publishing a statement that Antineoplastons have been proven safe for the treatment of cancers in humans.

6) Respondent publication of this statement is equivalent to publishing a statement that Antineoplastons have been proven effective for the treatment of cancers in humans.

7) Respondent's publication of this statement was an inaccurate statement.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

8) Respondent's publication of this statement was a misleading statement.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is

false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

9) Respondent's publication of this statement was a deceptive statement.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

14. Sometime between the date of the agreement with the FDA about the clinical studies and June 13, 2012, the following items were posted as material or hyperlinks on the www.burzynskiresearch.com website:

A. "Burzynski Research Institute Presents Positive Results from Phase 2 Trials of ANP for Inoperable Brainstem Glioma at the Congress (May 11, 2008)

"ANP was well-tolerated with easy manageable side effects of fatigue, skin rash and electrolyte abnormalities and no chronic toxicities...These results compared favorably to radiation therapy and chemotherapy (Mandell, et al. 1999, 7% overall survival at 2 years and 0% at 5 years), but should be confirmed in Phase 3 trials scheduled to begin in 2009."

1) Respondent reasonably was aware at the time of the continued posting of these statements as of June 13, 2013, that insufficient scientific evidence existed to support these statements indicating (1) that antineoplastons selectively attacked, killed or inhibited the growth of cancer cells in the

human body and (2) that antineoplastons did not harm healthy cells in the human body.

2) Respondent's posting of this statement was a publication.

3) Respondent's posting of this statement was an advertisement.

4) Respondent's publication of this statement was a promotional statement made in violation of 21 CFR 312.7(a).

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

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6) Respondent publication of this statement is equivalent to publishing a statement that Antineoplastons have been proven effective for the treatment of cancers in humans.

7) Respondent's publication of this statement was an inaccurate statement.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule

190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

8) Respondent's publication of this statement was a misleading statement.

Violation

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Violation

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connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

B. "Burzynski Research Institute Presents Positive Results from Phase 2 Trials of ANP for Inoperable Brainstem Glioma at the Congress (May 11, 2008)

"The remarkable response of one of the patients who was treated on the study protocol was the subject of the second presentation....She achieved complete response in February 1999 and continues to be tumor free and lives a normal life since then."

1) Respondent reasonably was aware at the time of the continued posting of these statements as of June 13, 2013, that insufficient scientific evidence existed to support these statements indicating (1) that antineoplastons selectively attacked, killed or inhibited the growth of cancer cells in the human body and (2) that antineoplastons did not harm healthy cells in the human body.

2) Respondent's posting of this statement was a publication.

3) Respondent's posting of this statement was an advertisement.

4) Respondent's publication of this statement was a promotional statement made in violation of 21 CFR 312.7(a).

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

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6) Respondent publication of this statement is equivalent to publishing a statement that Antineoplastons have been proven effective for the treatment of cancers in humans.

7) Respondent's publication of this statement was an inaccurate statement.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

8) Respondent's publication of this statement was a misleading statement.

Violation

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connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

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Violation

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C. Burzynski Research Institute Gets SPA Clearance from the FDA to initiate Pivotal Phase 3 trial of Combination Antineoplaston Therapy and Radiation Therapy (January 13, 2009)

"Antineoplaston therapy (ANP) uses a synthetic version of naturally occurring peptides and amino acid derivatives found in the human body to target and control cancer cells without destroying normal cells."

1) Respondent reasonably was aware at the time of the continued posting of these statements as of June 13, 2013, that insufficient scientific evidence existed to support these statements indicating (1) that antineoplastons selectively attacked, killed or inhibited the growth of cancer cells in the human body and (2) that antineoplastons did not harm healthy cells in the human body.

2) Respondent's posting of this statement was a publication.

3) Respondent's posting of this statement was an advertisement.

4) Respondent's publication of this statement was a promotional statement made in violation of 21 CFR 312.7(a).

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

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6) Respondent publication of this statement is equivalent to publishing a statement that Antineoplastons have been proven effective for the treatment of cancers in humans.

7) Respondent's publication of this statement was an inaccurate statement.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

8) Respondent's publication of this statement was a misleading statement.

Violation

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D. Thought Leaders from Burzynski Research Institute Inc. Present Encouraging Data on Antineoplastons for Treatment of Malignant Gliomas (November 20, 2008)

"ANP was well tolerated, with just two cases of serious reversible toxicities."

1) Respondent reasonably was aware at the time of the continued posting of these statements as of June 13, 2013, that insufficient scientific evidence existed to support these statements indicating (1) that antineoplastons selectively attacked, killed or inhibited the growth of cancer cells in the human body and (2) that antineoplastons did not harm healthy cells in the human body.
2) Respondent's posting of this statement was a publication.
3) Respondent's posting of this statement was an advertisement.
4) Respondent's publication of this statement was a promotional statement made in violation of 21 CFR 312.7(a).

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

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16. Respondent's internet-based advertising was false, misleading and violated federal law. The letter from the FDA dated October 18, 2012, alleged that Respondent's websites violated the Federal Food, Drug, and Cosmetic Act and FDA regulation 21 CFR 312.7(a). Respondent's websites did violate the Federal Food, Drug, and Cosmetic Act and FDA regulation 21 CFR 312.7(a). Respondent's violation of federal law connected with the practice of medicine constituted a violation of the Act and Board Rules.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

17. Respondent, as 80% owner of the Burzynski Institute and 100% owner of the Burzynski Clinic, failed to adequately and appropriately scrutinize his advertisements and adhere to appropriate ethical standards for truth in advertising.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 164.1, which prohibits the dissemination of information that is false,

deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; (2) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(H), referring a patient to a facility without disclosing the existence of the licensee's ownership interest in the facility, and (I) using false, misleading, or deceptive advertising; (3) Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive; and (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.3(b), 21 CFR 312.7(a), 21 CFR 312.50 and 21 CFR 312.60.

H. **Violation of FDA Regulations Regarding Phase 2 Clinical Studies**

1. Respondent was responsible as principal investigator and as sponsor for the performance of the Burzynski Clinic, Burzynski Research Institute, and Burzynski Research Institute-Institutional Research Board ("BRI-IRB") to be in compliance with FDA regulations pursuant to 21 CFR 312.3(b), 21 CFR 312.50 and 21 CFR 312.60.

2. A warning letter from the FDA dated October 5, 2009 informed Respondent that as principal investigator and sponsor he had failed to meet criteria for the protection of human subjects in clinical studies of products regulated by the FDA.

3. Respondent failed to do the following to protect the patients who were human subjects in the clinical studies of antineoplastons; (1) Respondent failed to take adequate measures to minimize risks to patients; and (2) Respondent failed to ensure that the risks to patients were reasonable in relation to anticipated benefits and the importance of the knowledge that may be expected to result.

4. On or about January 6, 2005, the BRI-IRB chairman notified Respondent that the clinical study protocols, including informed consent, would have to be modified and an investigator's brochure created before the BRI-IRB would approve the initiation of treatment of patients as human subjects.

5. Although a letter dated April 4, 2005, informed Respondent that the initiation of treatment was approved, Respondent's submission of modified protocols and consents and an investigator's brochure was not documented.

6. On or about January 10, 2007, the Respondent, as sponsor, principal investigator and member of the institutional review board (BRI-IRB) documented the BRI-IRB's readiness to approve initiation of treatment under the clinical studies after an opportunity to complete a review of an adequate clinical protocol, an adequate investigator's brochure, adequate information about the antineoplaston manufacturing process and adequate information about the potential effects, particularly Toxicity Studies, of antineoplastons on human subjects.

7. Respondent failed to document an adequate clinical protocol, an adequate investigator's brochure, adequate information about the antineoplaston manufacturing process and adequate information about the potential effects of antineoplastons on human subjects prior to February 1, 2008, that would enable reviewers to adequately evaluate safety and efficacy of the study before initiation of treatment.

Violation

(1) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2) and (2) 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, in particular 21 CFR 312.32(c); 21 CFR 312.50; 21 CFR 312.53; 21 CFR 312.55; 21 CFR 312.57, 21 CFR 312.60, 21 CFT 312.62; 21 CFR 312.64; 21 CFR 312.66; 21 CFR 312.110 and 21 CFR 312.120.

8. Respondent initiated treatment of patients as human subjects in the clinical studies of antineoplastons sometime between April 4, 2005 and February 1, 2008.

9. The BRI-IRB first received some of the requested information from Respondent regarding safety and efficacy to human subjects in the clinical studies of antineoplastons on or about February 1, 2008.

10. The BRI-IRB did not approve the clinical studies for initiation of treatment at that time.

11. On or about February 15, 2008, the BRI-IRB chairman requested that Respondent provide additional information and reminded that Respondent, as principal investigator, was required to report all adverse events that occurred for patients.

12. The BRI-IRB chairman also notified Respondent that the human studies were placed on hold until the requested information was received and reviewed by the BRI-IRB. Respondent ignored these communications, despite his membership on the BRI-IRB.

13. Respondent had actually initiated treatment of patients in the clinical studies of antineoplastons before February 1, 2008, and he continued that treatment after February 1, 2008, without providing this additional requested information to the BRI-IRB.

14. Respondent's initiation of treatment of patients in a clinical study prior to the preliminary, conditional approval of the BRI-IRB constituted a violation of federal law and regulations.

Violation

(1) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2) and (2) 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, in particular 21 CFR 312.32(c); 21 CFR 312.50; 21 CFR 312.53; 21 CFR 312.55; 21 CFR 312.57, 21 CFR 312.60, 21 CFT 312.62; 21 CFR 312.64; 21 CFR 312.66; 21 CFR 312.110 and 21 CFR 312.120.

15. Respondent's initiation of treatment of patients in a clinical study prior to the preliminary, conditional approval of the BRI-IRB constituted a violation of the standard of care.

16. As part of Respondent's application for antineoplastons as an investigational new drug, Respondent included protocols for use of a device that might be a "significant risk device" pursuant to federal regulations. 21 CFR 812.66.1

17. The BRI-IRB, the sponsor and principal investigator had a responsibility to determine whether this "device" involved "significant risk" as defined by federal regulations.

18. Respondent, as a sponsor and as an investigator, had a responsibility to present and document information whether this device involved "significant risk" as defined by federal regulations.

19. Respondent, as a sponsor and as an investigator, failed to present and document information to the BRI-IRB about the significant risk of this device.

20. Respondent's failure violated federal regulations. The BRI-IRB approved the initiation of patient treatment with antineoplastons despite the inadequate review and determination of a significant risk device and Respondent's failure.

Violation

> (1) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2) and (2) 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, in particular 21 CFR 312.32(c); 21 CFR 312.50; 21 CFR 312.53; 21 CFR 312.55; 21 CFR 312.57, 21 CFR 312.60, 21 CFT 312.62; 21 CFR 312.64; 21 CFR 312.66; 21 CFR 312.110 and 21 CFR 312.120.

21. As part of Respondent's application for antineoplastons as an investigational new drug, Respondent included protocols for informed consent documents pursuant to federal regulations. 21 CFR 50.27 and 21 CFR 56.111

22. The BRI-IRB had a responsibility to determine whether informed consent documents submitted by Respondent, as a sponsor and as an investigator, were in accordance with federal regulations.

23. Respondent, as a sponsor and as an investigator, had a responsibility to submit informed consent documents that were in accordance with federal regulations.

24. Respondent, as a sponsor and as an investigator, failed to present information to the BRI-IRB about adequacy of the informed consent documents being used for the clinical studies of antineoplastons. Respondent's failure violated federal regulations.

Violation

> (1) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2) and (2) 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, in particular 21 CFR 312.32(c); 21 CFR 312.50; 21 CFR 312.53; 21 CFR 312.55; 21 CFR 312.57, 21 CFR 312.60, 21 CFT 312.62; 21 CFR 312.64; 21 CFR 312.66; 21 CFR 312.110 and 21 CFR 312.120.

25. The BRI-IRB approved the initiation of patient treatment with antineoplastons despite the inadequate review of informed consent documents and Respondent's failure.

26. Federal regulations prohibited Respondent, as a sponsor and as an investigator, to participate in discussions and vote at BRI-IRB meetings if there was a review of a matter in which Respondent had a potential conflict of interest.

27. At several meetings of the BRI-IRB, Respondent participated in reviews, discussions and decision-making votes in violation of this prohibition.

28. Respondent's participation in the BRI-IRB in violation of federal regulation prohibitions regarding conflict of interest demonstrated that the BRI-IRB was not independent from Respondent's direction and control.

Violation

(1) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2) and (2) 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, in particular 21 CFR 312.32(c); 21 CFR 312.50; 21 CFR 312.53; 21 CFR 312.55; 21 CFR 312.57, 21 CFR 312.60, 21 CFT 312.62; 21 CFR 312.64; 21 CFR 312.66; 21 CFR 312.110 and 21 CFR 312.120.

29. The minutes of the BRI-IRB from 2005 through 2013, further demonstrate that that the BRI-IRB was not independent from Respondent's direction and control.

30. Federal regulations required the BRI-IRB to conduct continuing reviews of any approved clinical studies.

31. Despite issuing letters of approval to Respondent in March and April 2005 and February 2008, the BRI-IRB did not review any of the clinical studies that Respondent initiated between March 2005 and April 2009.

32. The BRI-IRB informed the FDA that there had been no review of the clinical studies already in progress because Respondent, as a sponsor and as an investigator, had not provided information from those studies to review.

33. Respondent, as a sponsor and as an investigator, had a responsibility to provide information from clinical studies in progress for BRI-IRB to review. Respondent's failure violated federal law and regulations.

Violation

(1) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2) and (2) 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, in particular 21 CFR 312.32(c); 21 CFR 312.50; 21 CFR 312.53; 21 CFR 312.55; 21 CFR 312.57, 21 CFR 312.60, 21 CFT 312.62; 21 CFR 312.64; 21 CFR 312.66; 21 CFR 312.110 and 21 CFR 312.120.

34. The FDA issued a letter dated September 23, 2013, to Respondent and BRI-IRB imposing restrictions on Respondent and BRI-IRB from enrolling patients as human subjects in clinical studies of antineoplastons. These restrictions were issued due to the failure of Respondent and BRI-IRB to adequately address allegations based on FDA inspection reports that Respondent and BRI-IRB had violated federal regulations related to those clinical studies.

35. The FDA found Respondent's written responses dated February 28, 2013 and March 28, 2013, to the inspection report of early 2013 to be unacceptable.

36. The FDA informed Respondent and BRI-IRB that a corrective action plan was required to adequately address allegations based on FDA inspection reports that Respondent and BRI-IRB had violated federal regulations related to Respondent's clinical studies of antineoplastons.

37. The federal regulatory requirements for approval of single patient protocols for Phase 1 or Phase 2 clinical studies require ensuring that risks to patient/subjects are minimized and reasonable in relation to anticipated benefits.

38. Ensuring that risks to patient/subjects are minimized and reasonable in relation to anticipated benefits requires (1) review of the subject's medical records (history and physical examination) and (2) clarifying any outstanding issues with respect to the suitability of treating the patient/subject prior to granting institutional review board approval.

39. Initiation of treatment of a patient in such a clinical study without proper approval of the institutional review board violates federal regulations.

40. BRI-IRB used the expedited review process, provided in federal regulations, inappropriately to approve protocols for patients who failed to meet enrollment criteria for antineoplaston therapy clinical studies.

41. Only physicians who had clinical expertise necessary to make the required information evaluation of potential risks and anticipated benefits could professionally evaluate applicant patients regarding enrollment criteria and protocols related to medical condition, risk of treatments and benefits of treatments.

42. BRI-IRB members who were not physicians with adequate clinical experience had placed these patients on "provisional approval" before review by the BRI-IRB.

43. Respondent had initiated treatment of these patients in clinical studies prior to obtaining the approval of BRI-IRB at a board meeting, as required by federal regulations.

44. Respondent's initiation of treatment of these "provisional approval" patients before review and vote by the BRI-IRB violated federal regulations. These illegally initiated patients included: Patient H, Patient I, Patient J, Patient K, and Patient L,

Violation

> (1) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2) and (2) 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, in particular 21 CFR 312.32(c); 21 CFR 312.50; 21 CFR 312.53; 21 CFR 312.55; 21 CFR 312.57, 21 CFR 312.60, 21 CFT 312.62; 21 CFR 312.64; 21 CFR 312.66; 21 CFR 312.110 and 21 CFR 312.120.

45. BRI-IRB also used their version of the expedited review process inappropriately to review the assessment of risks to patient/subjects, the balancing of risks and anticipated benefits and the knowledge that may be expected to result for patients to meet enrollment criteria for antineoplaston therapy clinical studies.

47. BRI-IRB members who were not physicians with adequate clinical experience had placed these patients on "provisional approval" before review by the BRI-IRB.

48. Respondent had initiated treatment of these patients in clinical studies prior to review by a physician member of the BRI-IRB and prior to obtaining the approval of BRI-IRB at a board meeting, as required by federal regulations.

49. Respondent's initiation of treatment of these "provisional approval" patients before review and vote by the BRI-IRB violated federal regulations. These illegally initiated patients included: Patient M, Patient N, Patient O, and Patient P.

Violation

(1) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2) and (2) 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, in particular 21 CFR 312.32(c); 21 CFR 312.50; 21 CFR 312.53; 21 CFR 312.55; 21 CFR 312.57, 21 CFR 312.60, 21 CFT 312.62; 21 CFR 312.64; 21 CFR 312.66; 21 CFR 312.110 and 21 CFR 312.120.

50. Respondent, as a sponsor and as an investigator, had initiated treatment of several child patients in clinical studies of antineoplastons in violation of federal regulations.

51. Federal regulations prohibit initiation of clinical studies for child patients until the institutional review board has granted approval after reviewing those applicants regarding the criteria of federal regulations to provide extra protection for children. See 21 CFR 50.50, 21, CFR 50.51, 21 CFR 50. 52, 21 CFR 50.53, 21 CFR 56.109(h)

52. The BRI-IRB approved several child patients for antineoplaston clinical studies without documentation that the study did not involve greater than a minimal risk to the patient/subject, that the study presented the prospect of direct benefit to the patient/subject, or any risk greater than minimal risk and insufficient direct benefit to the patient/subject would yield generalizable knowledge about the subject's disorder or condition.

53. Respondent failed to provide this information to the BRI-IRB when submitting these patients for approval. Respondent's initiation of the treatment of the following children

without documenting the special safeguards for child patients violated federal regulations. Those child patients included the following: Patient I, Patient J, and Patient H.

54. The FDA rejected Respondent's proposal of an alternate procedure for BRI-IRB to circumvent the federal requirements for expedited review of applicants for clinical studies and for consideration of safeguards for children.

55. The FDA reiterated that these expedited reviews were limited to patients with serious or immediately life-threatening diseases of conditions who lack therapeutic alternatives.

56. The FDA placed a hold on BRI-IRB from approving any new clinical studies on children and any new clinical studies using the expedited review process.

57. FDA inspections are designed to evaluate the conduct of FDA-regulated research to ensure that the data are scientifically valid and accurate, and to help ensure that the rights, safety and welfare of human subjects of those studies have been protected.

58. Respondent, as a sponsor-investigator of a clinical study, was and continues to be required to ensure that clinical studies under this direction and control are conducted in accordance with the investigational plans that include the protocols submitted to the FDA.

59. The investigational plans for clinical studies of antineoplastons designated as Protocols BT-09, BT-10, and BT-21 required Respondent, as a sponsor and as an investigator, to only report therapeutic responses based on how the patients/subjects' tumors respond to the study drug.

60. The investigational plans for clinical studies of antineoplastons designated as Protocols BT-09, BT-10, and BT-21 required Respondent, as a sponsor and as an investigator to report adverse response events of the patients/subjects.

61. The adverse events that Respondent, as a sponsor and as an investigator, was required to report included overdoses of the investigational new drug.

62. Respondent failed to adequately document adverse events for the following patients: Patient Q, Protocol B-10; Patient R, Protocol B-10; Patient S, Protocol B-10; Expanded access Patient T, Protocol B-10; Patient U, Protocol AD-02.

Violation

(1) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2) and (2) 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, in particular 21 CFR 312.32(c); 21 CFR 312.50; 21 CFR 312.53; 21 CFR 312.55; 21 CFR 312.57, 21 CFR 312.60, 21 CFT 312.62; 21 CFR 312.64; 21 CFR 312.66; 21 CFR 312.110 and 21 CFR 312.120.

63. Respondent, as a sponsor-investigator of a clinical study, was and continues to be required to ensure that persons under his direction and control providing care to the patients in a clinical study are adequately trained or retrained after adverse events, such as overdose of the investigational new drug.

64. After Respondent was notified of adverse events for these patients, he failed to adequately train or re-train those persons under his direction and control. Respondent violated federal regulations and the standard of care in this regard for the following patients: Patient Q, Protocol B-10; Patient R, Protocol B-10; Patient S, Protocol B-10; Expanded access Patient T, Protocol B-10; and Patient U, Protocol AD-02.

65. The investigational plans for clinical studies of antineoplastons designated as Protocols BT-09, BT-10, and BT-21 required Respondent, as a sponsor and as an investigator, to consider and report the effect of corticosteroids on patient responses to the investigational new drug.

67. The investigational plans and protocols required that a therapeutic response could only be characterized as a "complete response" when the patients had no longer been taking corticosteroids during the time period for which the tumor response was measured.

68. Many of the patients for which Respondent provided inaccurate reports of tumor response were receiving corticosteroids during the time period for which the tumor response was measured.

69. These patients were receiving corticosteroids under Respondent's recommendations and direction that exceeded those dosages needed to maintain physiologic levels.

70. The investigational plans for clinical studies of antineoplastons designated as Protocols BT-09, BT-10, and BT-21 required Respondent, as a sponsor and as an investigator to ensure that protocols were followed to isolate the impact of corticosteroids on tumor response in order to obtain scientifically valid information from the clinical studies.

71. Failure to assess tumor response in accordance with the protocol requirements jeopardizes subject safety and welfare and raises concerns about the validity and integrity of the data collected in a clinical study.

72. Ensuring that protocols were followed to isolate the impact of corticosteroids on tumor response is crucial to the sponsor-investigator's responsibility to ensure that complete and accurate data obtained regarding the safety, efficacy and benefits of the study drug.

73. Respondent's failure to ensure that protocols were followed constitutes a violation of federal regulations.

Violation

(1) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2) and (2) 164.053(a)(1) of the Act,

commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, in particular 21 CFR 312.32(c); 21 CFR 312.50; 21 CFR 312.53; 21 CFR 312.55; 21 CFR 312.57, 21 CFR 312.60, 21 CFT 312.62; 21 CFR 312.64; 21 CFR 312.66; 21 CFR 312.110 and 21 CFR 312.120.

74. Respondent assigned therapeutic responses incorrectly for 9 of 27 (one out of three) subjects reviewed during inspection, including the following:

Patient V, Protocol BT-10
Patient R, Protocol BT-10
Patient W, Protocol BT-09
Patient X, Protocol BT-21
Patient Y, Protocol BT-09
Patient Q, Protocol BT-10
Patient Z, Protocol BT-10
Patient AA, Protocol BT-10
Patient BB, Protocol BT-10

75. Respondent, as a sponsor-investigator of a clinical study, failed to ensure that Protocols BR-09, BT-10 and BT-21 were conducted according to the investigational plans.

76. Respondent's failure to ensure that Protocols BR-09, BT-10 and BT-21 were conducted according to the investigational plans violated federal regulations.

Violation

(1) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2) and (2) 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, in particular 21 CFR 312.32(c); 21 CFR 312.50; 21 CFR 312.53; 21 CFR 312.55; 21 CFR 312.57, 21 CFR 312.60, 21 CFT 312.62; 21 CFR 312.64; 21 CFR 312.66; 21 CFR 312.110 and 21 CFR 312.120.

77. Respondent, as a sponsor-investigator of a clinical study, was and continues to be required to ensure that patients in the clinical studies were provided informed consent in accordance with federal regulations.

78. The consent forms that Respondent approved for use in the clinical studies under Protocol B-10 and B-22 were inadequate and violated federal regulations due to the lack of a statement informing the patient of any additional costs.

79. Failure to provide subjects with information regarding any additional costs prior to obtaining informed consent denies subjects the opportunity to make an informed decision regarding their participation in the clinical investigation.

80. Respondent only presented a billing agreement to applicant patients/subjects after they had already consented to participate in the clinical studies. Respondent's failure to obtain adequate informed consent constituted a violation of federal regulations, the Act and Board Rules.

81. Respondent, as a sponsor-investigator of a clinical study, was and continues to be required to ensure that the clinical study maintain accurate case histories and records.

82. Respondent failed to maintain adequate and accurate case histories for Patient CC, Special Protocol Exception to Protocol B-10.

Violation

(1) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2) and (2) 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, in particular 21 CFR 312.32(c); 21 CFR 312.50; 21 CFR 312.53; 21 CFR 312.55; 21 CFR 312.57, 21 CFR 312.60, 21 CFT 312.62; 21 CFR 312.64; 21 CFR 312.66; 21 CFR 312.110 and 21 CFR 312.120.

83. Respondent provided the FDA inspectors with notably different records for Patient CC than were provided to the FDA previously.

84. Respondent's failure to maintain adequate and accurate medical records for patients/subjects in a clinical study violated federal regulations, the Act and Board Rules.

86. During the period January 17, 2013, through March 15, 2013, multiple violations of FDA regulations were cited by FDA inspectors in regard to the S.R. Burzynski Study Monitoring Plan after an inspection of documents of the Burzynski Clinic, Burzynski Research Institute, and Burzynski Research Institute-IRB, regarding the S.R. Burzynski Study Monitoring Plan MQA-001 Revision A (Monitoring Plan).

87. The FDA inspectors' reports in early 2013 had revealed that Respondent, in violation of FDA regulations, had not conducted the investigation evaluation, diagnosis and treatment of the patients in the clinical studies related to investigational new drugs in accordance with FDA regulations and the signed agreement of the sponsor, the principal investigator and investigation review board due to the following:

a. Respondent and persons under his direction and supervision failed to follow investigation protocols;

b. Respondent and persons under his direction and supervision failed to report all adverse events experienced by study subjects during their participation in the studies to the sponsor as required by the study protocols;

c. Respondent and persons under his direction and supervision failed to protect the rights, safety, and welfare of subjects under his care;

d. Respondent and persons under his direction and supervision failed to prepare or maintain adequate case histories with respect to observations and data pertinent to the investigation;

e. Respondent and persons under his direction and supervision failed to report promptly to the IRB all unanticipated problems involving the risk to human subjects or others, such as study subjects/patients being admitted to hospital due to side effects of the investigational new drugs;

f. Respondent and persons under his direction and supervision failed to obtain adequate informed consent from the study subjects/patients, as it did not include a statement of any additional costs to the subject that might result from participation in the research;

g. Respondent and persons under his direction and supervision failed to maintain adequate records of the investigational drug disposition with respect to quantity and use by subjects;

h. Respondent and persons under his direction and supervision failed to conduct dynamic audits since 2005, as required by his Monitoring Plan; and

i. Respondent and persons under his direction and supervision failed to maintain adequate records required (FDA Form 1572) for "local physicians" who participated in the clinical study activities involving evaluation, diagnosis and treatment of the study subjects/patients.

j. Respondent failed to have QA (quality assurance) monitor the Monitoring Plan Section 7.2.1 regarding "monitor clinical trials including source document verification, query report general and final resolution, and drug accountability." Monitoring Plan Section 7.2.2 the QA monitor ensure that Respondent's obligations are met and in compliance with FDA regulations. Monitoring Plan Section 7.2.3, required that the QA monitor reviewed and analyzed case report forms (CRF's) and subject charts for clarity, content, and data integrity.

k. Respondent failed to monitor as required: Monitoring Plan Section 13.1.1 required that Monitoring and Quality Assurance Department (MQA) ensured all subjects that participated in the consenting process are provided with a consent form describing the study. Furthermore, Monitoring Plan Section 13.1.2 required that the MQA verify that a subject's consent was obtained before the subject undergoes any study procedure.

l. Respondent failed to monitor as required by Monitoring Plan Section 16 which stated staff to "verify that information on all adverse events (AE) are "...summarized in the CRF's on monthly basis." Respondent failed to report AE's experienced by study subjects, including 18 cases of hypernatremia.

m. Respondent was required by the monitoring plan in Monitoring Plan Section 11 to ensure that a signed Form FDA 1572 and curriculum vitae (CV) are obtained from each "local physician". The documents for 65 % of the "local

physicians" were missing. Specifically, a random selection of 20 "local physicians" from Respondent's list revealed that he didn't have a CV for 13 of the 20 that were randomly selected.

n. Respondent was also found to be in violation for failure to obtain financial information to allow complete and accurate certification of disclosure statements. Specifically, Respondent failed to provide upon request financial information for each of the sub-investigators participating in studies and to allow for complete and accurate certification or disclosure statements.

o. On or about December 3, 2013, the FDA issued a warning letter to Respondent citing the FDA inspectors' report and that all of the above investigational findings were adopted by the FDA Office of Compliance considering the current investigation and history of past investigations.

88. Prior to January 17, 2013, Respondent and persons under his direction and control participated in the evaluation, diagnosis and treatment of multiple patients with investigational new drugs, including antineoplastons. Respondent and persons under his direction and control violated federal laws, FDA regulations and the signed agreement of the sponsor, the principal investigator and investigation review board; (1) as relates to the evaluation and treatment of the patients whose records were reviewed as part of the FDA inspectors' 2013 report issued during the period January 17, 2013, through March 15, 2013, and (2) as relates to the evaluation and treatment of the patients in this case who were treated with investigational new drugs, including antineoplastons. Respondent and persons under his direction and control violated federal laws, federal regulations and the clinical study agreements with the FDA connected with the practice of medicine, including the following: See 21 CFR 312.32(c); 21 CFR 312.50; 21 CFR 312.53; 21 CFR 312.55; 21 CFR 312.57, 21 CFR 312.60, 21 CFT 312.62; 21 CFR 312.64; 21 CFR 312.66; 21 CFR 312.110 and 21 CFR 312.120.

Violation

(1) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2) and (2) 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected

with the physician's practice of medicine, in particular 21 CFR 312.32(c); 21 CFR 312.50; 21 CFR 312.53; 21 CFR 312.55; 21 CFR 312.57, 21 CFR 312.60, 21 CFT 312.62; 21 CFR 312.64; 21 CFR 312.66; 21 CFR 312.110 and 21 CFR 312.120.

89. Prior to January 17, 2013, Respondent and persons under his direction and control participated in the evaluation, diagnosis and treatment of multiple patients with investigational new drugs, including antineoplastons. Respondent and persons under his direction and control violated federal laws, FDA regulations and the signed agreement of the sponsor, the principal investigator and investigation review board; (1) as relates to the evaluation and treatment of the patients whose records were reviewed as part of the FDA inspectors' 2013 report issued during the period January 17, 2013, through March 15, 2013, and (2) as relates to the evaluation and treatment of the patients in this case who were treated with investigational new drugs, including antineoplastons. Respondent failed to adequately supervise these employees and delegated medical tasks to several employees who were not appropriately trained and licensed to perform those tasks. Respondent's conduct and his failure to adequately supervise constituted a failure to meet his responsibilities as sponsor and principle investigator, and therefore, violated the Act and federal regulations.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); (3) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2); (4) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.32(c); 21 CFR 312.50; 21 CFR 312.53; 21 CFR 312.55; 21 CFR 312.57, 21 CFR 312.60, 21 CFT 312.62; 21 CFR 312.64; 21 CFR 312.66; 21 CFR 312.110 and 21 CFR 312.120; (5) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician; and (6) Section 164.053(a)(9) of the Act, delegation of professional medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not qualified by training, experience or licensure to perform the responsibility or acts.

90. Prior to January 17, 2013, Respondent and persons under his direction and control participated in the evaluation, diagnosis and treatment of multiple patients with investigational new drugs, including antineoplastons. Respondent and persons under his direction and control

violated federal laws, FDA regulations and the signed agreement of the sponsor, the principal investigator and investigation review board; (1) as relates to the evaluation and treatment of the patients whose records were reviewed as part of the FDA inspectors' 2013 report issued during the period January 17, 2013, through March 15, 2013, and (2) as relates to the evaluation and treatment of the patients in this case who were treated with investigational new drugs, including antineoplastons. Respondent's direction of the evaluation, diagnosis and treatment of those patients in violation of FDA regulations and the signed agreement of the sponsor, the principal investigator and investigation review board violated the standard of care for a physician acting as a principal investigator and sponsor of a clinical study. .

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; and (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); 190.8(1)(D); (3) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine; (4) Section 164.053(a)(5) of the Act, prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed; and (5) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician.

91. Prior to January 17, 2013, Respondent and persons under his direction and control participated in the evaluation, diagnosis and treatment of multiple patients with investigational new drugs, including antineoplastons. Respondent and persons under his direction and control violated federal laws, FDA regulations and the signed agreement of the sponsor, the principal investigator and investigation review board; (1) as relates to the evaluation and treatment of the patients whose records were reviewed as part of the FDA inspectors' 2013 report issued during the period January 17, 2013, through March 15, 2013, and (2) as relates to the evaluation and treatment of the patients in this case who were treated with investigational new drugs, including antineoplastons. Respondent's direction of the evaluation, diagnosis and treatment of those patients in violation of FDA regulations and the signed agreement of the sponsor, the principal investigator and investigation review board violated the standards of adequate documentation for a physician acting as a principal investigator and sponsor of a clinical study.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; and (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); (3) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.32(c); 21 CFR 312.50; 21 CFR 312.53; 21 CFR 312.55; 21 CFR 312.57, 21 CFR 312.60, 21 CFT 312.62; 21 CFR 312.64; 21 CFR 312.66; 21 CFR 312.110 and 21 CFR 312.120.

92. Prior to January 17, 2013, Respondent and persons under his direction and control participated in the evaluation, diagnosis and treatment of multiple patients with investigational new drugs, including antineoplastons. Respondent and persons under his direction and control violated federal laws, FDA regulations and the signed agreement of the sponsor, the principal investigator and investigation review board; (1) as relates to the evaluation and treatment of the patients whose records were reviewed as part of the FDA inspectors' 2013 report issued during the period January 17, 2013, through March 15, 2013, and (2) as relates to the evaluation and treatment of the patients in this case who were treated with investigational new drugs, including antineoplastons.

93. Respondent, as principal investigator and sponsor of the investigational new drug, antineoplastons, was responsible for the failure of those persons under his direction and control to comply with standards of adequate documentation. Respondent failed to adequately supervise these employees and delegated medical tasks of documentation to several employees who were not appropriately trained and licensed to perform those tasks.

Violation

(1) Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; (2) Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); (3) Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.32(c); 21 CFR 312.50; 21 CFR 312.53; 21 CFR 312.55; 21 CFR 312.57, 21 CFR 312.60, 21 CFT 312.62; 21 CFR 312.64; 21 CFR 312.66; 21 CFR 312.110 and 21 CFR 312.120; (4) Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician; and (5) Section 164.053(a)(9) of the Act, delegation of professional

medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not qualified by training, experience or licensure to perform the responsibility or acts.

IV. STATUTORY VIOLATIONS

The actions of Respondent specified above violate one or more of the following provisions of the Act:

1. Section 157.001 of the Act provides that a physician is responsible for medical acts delegated to qualified and properly trained persons acting under the physician's supervision.

2. Section 157.002 of the Act provides that a physician is responsible for the supply and administration of dangerous drugs by qualified and properly trained persons acting under the physician's supervision.

3. Section 164.051(a)(1) of the Act authorizes the Board to take disciplinary action based on Respondent's commission of an act prohibited under Section 164.052 of the Act.

4. Section 164.051(a)(3) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's violation of a Board Rule(s), specifically, Board Rules: 165.1, requiring a physician to maintain adequate medical records; 164.1, which prohibits the dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3; prohibiting the use of misleading or deceptive advertising; 193.1, inadequate supervision and aiding and abetting the unauthorized practice of medicine, 193.5, physician liability for delegated acts; 200.1 through 200.3, regarding guidelines for the practice of alternative and complementary medicine.

5. Section 164.051(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's failure to practice medicine in an acceptable professional manner consistent with public health and welfare, generally, and as further defined by Board Rules: 190.8(1)(A), failure to treat a patient according to the generally accepted standard of care; 190.8(1)(B), negligence in performing medical services; 190.8(1)(C), failure to use proper diligence in one's professional practice; 190.8(1)(D), failure to safeguard against potential complications; 190.8(1)(G), failure to disclose reasonably foreseeable side effects of a

procedure or treatment; 190.8(1)(H), failure to disclose reasonable alternative treatments to a proposed procedure or treatment; and 190.8(1)(I), failure to obtain informed consent.

6. Section 164.052(a)(5) of the Act authorizes the Board to take disciplinary action against Respondent based upon Respondent's unprofessional or dishonorable conduct that is likely to deceive or defraud the public or injure the public, as further defined by, Board Rules 190.8(2)(I), using false, misleading or deceptive advertising and 190.8(2)(J), providing medically unnecessary services to a patient.

7. Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive.

8. Section 164.053(a)(1) of the Act authorizes the Board to take disciplinary action against Respondent based upon Respondent's commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, specifically, Health and Safety Code, Section 311.0025 (a) of the Texas Health and Safety Code, prohibiting a hospital, treatment facility, mental health facility, or health care professional, from submitting to a patient or a third party payor, a bill for a treatment that the hospital, facility, or professional knows was not provided or knows was improper, unreasonable, or medically or clinically unnecessary and the following federal regulations:

> 21 CFR 312.7(a). 21 CFR 312.32(c); 21 CFR 312.50; 21 CFR 312.53; 21 CFR 312.55; 21 CFR 312.57, 21 CFR 312.60, 21 CFT 312.62; 21 CFR 312.64; 21 CFR 312.66; 21 CFR 312.110 and 21 CFR 312.120.

9. Section 164.053(a)(5) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent prescribing or administering a drug or treatment that is non-therapeutic in nature or non-therapeutic in the manner the drug or treatment is administered or prescribed.

10. Section 164.053(a)(8) of the Act authorizes the Board to take disciplinary action against Respondent based upon Respondent's failure to supervise adequately the activities of those acting under the supervision of the physician. Such failure may include a failure to meet the responsibility of the physician for the actions of delegatees pursuant to Section 157.001 and 157.002 of the Act.

11. Section 164.053(a)(9) of the Act authorizes the Board to take disciplinary action against Respondent based upon Respondent's delegation of professional medical responsibility or acts to a person if Respondent knew or had reason to know that the person was not qualified by training, experience, or licensure to perform the responsibility or acts.

V. AGGRAVATING FACTORS:

Under Texas Administrative Code, Title 22, Part 9, Board Rule 190.15(a), in any disciplinary action, aggravating factors that warrant more severe or restrictive action by the Board may be considered by the Board. This case includes the following aggravating factors:

1. harm to one or more patients;
2. severity of patient harm;
3. one or more violations that involve more than one patient;
4. increased potential harm to the public;
5. prior similar violations, and
6. previous disciplinary action by the Board, specifically, on August 20, 1994, the Board entered an Order (1994 Order) that suspended Respondent's medical license, stayed the suspension, and placed Respondent on probation for a period of 10 years. The Board's action was based on Respondent's treating patients with acquired immune deficiency syndrome and cancer with anitineoplastons, in violation of state and federal laws. The 1994 Order terminated on October 19, 2004.

VI. APPLICABLE STATUTUES, RULES AND AGENCY POLICY

The following Statutes, Rules, and Agency Policy are applicable to the procedures for conduct of the hearing this matter:

1. Section 164.007(a) of the Act requires that the Board adopt procedures governing formal disposition of a contested case before the State Office of Administrative Hearings.
2. 22 Tex. Admin. Code, Chapter 187 sets forth the procedures adopted by the Board under the requirement of Section 164.007(a) of the Act.

3. 22 Tex. Admin. Code, Chapter 190 sets forth aggravating factors that warrant more severe or restrictive action by the board.
4. 1 Tex. Admin. Code, Chapter 155 sets forth the rules of procedure adopted by SOAH for contested case proceedings.
5. 1 Tex. Admin. Code, Chapter 155.507, requires the issuance of a Proposal for Decision (PFD) containing Findings of Fact and Conclusions of Law.
6. Section 164.007(a) of the Act, Board Rule 187.37(d)(2) and, Board Rule 190 et. seq., provide the Board with the sole and exclusive authority to determine the charges on the merits, to impose sanctions for violation of the Act or a Board rule, and to issue a Final Order.

VII. NOTICE TO RESPONDENT

IF YOU DO NOT FILE A WRITTEN ANSWER TO THIS COMPLAINT WITH THE STATE OFFICE OF ADMINISTRATIVE HEARINGS WITHING 20 DAYS AFTER THE DATE OF RECEIPT, A DEFAULT ORDER MAY BE ENTERED AGAINST YOU, WHICH MAY INCLUDE THE DENIAL OF LICENSURE OR ANY OR ALL OF THE REQUESTED SANCTIONS, INCLUDING THE REVOCATION OF YOUR LICENSE. A COPY OF ANY ANSWER YOU FILE WITH THE STATE OFFICE OF ADMINISTRATIVE HEARINGS SHALL ALSO BE PROVIDED TO THE HEARINGS COORDINATOR OF THE TEXAS MEDICAL BOARD.

VIII. PRAYER

WHEREFORE, PREMISES CONSIDERED, Board Staff requests that an administrative law judge employed by the State Office of Administrative Hearings conduct a contested case hearing on the merits of the Complaint, and issue a Proposal for Decision ("PFD") containing Findings of Fact and Conclusions of Law necessary to support a determination that Respondent violated the Act as set forth in this Complaint.

Respectfully submitted,

CHRISTOPHER PALAZOLA
Litigation Manager
SUSAN RODRIGUEZ

Lead Staff Attorney

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Austin, Texas 78701

THE STATE OF TEXAS §
§
COUNTY OF TRAVIS §

SUBSCRIBED AND SWORN to before me by the said Lee Bukstein on this 9th day of JULY, 2014.

CHEMECKIA LESHAE CADDELL
Notary Public, State of Texas
My Commission Expires
May 12, 2018

Notary Public, State of Texas

Filed with the Texas Medical Board on this 8th day of July, 2014.

Mari Robinson, J.D.
Executive Director
Texas Medical Board

CERTIFICATE OF SERVICE

I certify that on the 9th day of July, 2014, a true and correct copy of the foregoing document has been served as follows:

VIA COURIER BY HAND DELIVERY
Docket Clerk
State Office of Administrative Hearings
William P. Clements Bldg.
300 W. 15th Street, Suite 504
Austin, Texas 78701-1649

VIA FIRST CLASS MAIL AND CERTIFIED MAIL/RRR NO. 7008 2810 0000 1319 6954
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Lee Bukstein, J.D.